

## **EXHIBIT 1**

**Applicants: Harold J. Wanebo and Shashikant Mehta**

**U.S. Serial No.: 09/287,884**

**Filed: April 7, 1999**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Harold J. Wanebo and Shashikant Mehta  
U.S. Serial No.: 09/287,884 Examiner: J.D. Anderson  
Filed: April 7, 1999 Group Art Unit: 1614  
For: COMBINATIONS OF CERAMIDE AND CHEMOTHERAPEUTIC  
AGENTS FOR INDUCING CELL DEATH AND USES THEREOF  
IN TREATING CANCER

30 Rockefeller Plaza  
New York, New York 10112

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. §1.132

I, Harold J. Wanebo, M.D., hereby declare that:

1. I am a co-inventor named in the above-identified patent application.
2. I am also presently the Chief of Surgical Oncology at Landmark Medical Center in Woonsocket, RI. A copy of my curriculum vitae is attached hereto as **EXHIBIT A**.
3. I have reviewed and am familiar with the subject application, including pending claims 20-33. I understand that pending claims 20-24 provide methods for inhibiting growth of a tumor in a specific type of cancer cell comprising contacting the cell with an amount of paclitaxel and an amount of C<sub>6</sub>-ceramide, sequentially or concomitantly. I also understand that pending claims 25-29 provide methods for decreasing the size of a specific type of tumor comprising contacting the tumor with an amount of paclitaxel and an amount of C<sub>6</sub>-ceramide, sequentially or concomitantly. I further understand that pending claim 30 provides a pharmaceutical composition comprising paclitaxel, C<sub>6</sub>-ceramide and a pharmaceutically

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**Exhibit 1**

acceptable carrier. Finally, I understand that pending claims 31-33 provide methods for treating a subject afflicted with a specific type of cancer comprising administering to the subject an amount of paclitaxel and an amount of C<sub>6</sub>-ceramide, sequentially or concomitantly.

4. I have read and am familiar with the February 15, 2008 Office Action issued by the United States Patent and Trademark Office in connection with the subject application. I understand that in the Office Action, the Examiner rejected claims 20, 25, 30-31 under 35 U.S.C. §103(a) as allegedly unpatentable over Jayadev et al. (J. Biol. Chem., 1995, vol. 270, pages 2047-2052) in view of Mycek et al. (Lippincott's Illustrated Review: Pharmacology 2<sup>nd</sup> Edition, 1997, pages 376 and 390-392). I understand that in the Office Action, the Examiner rejected claims 20-33 under 35 U.S.C. §103(a) as allegedly unpatentable over Spencer et al. (Drugs, 1994, vol. 48, pages 794-847) in view of Cai et al. (J. Biol. Chem., 1997, vol. 272, pages 6918-6926).
5. Specifically, I understand that as a basis for this rejection, the Examiner asserts that no evidence of record shows that the combination of paclitaxel and C<sub>6</sub>-ceramide is synergistic in its effect on cancer.
6. I and/or Shashikant Mehta and/or individuals acting under our direction performed the following *in vivo* experiments to test the combined effects of paclitaxel and C<sub>6</sub>-ceramide. SCID/Beige/Taconic male mice (22-25 grams, 6-8 weeks old) (Taconic Laboratory, Germantown, NY, USA) were each inoculated with 2 x 10<sup>6</sup> L3.6 human pancreatic adenocarcinoma ("PA") cells subcutaneously in the internal surface of the right thigh. Four days later, when the mice developed primary tumors, chemotherapy was commenced by injecting the mice intraperitoneally with C<sub>6</sub>-ceramide (also referred to as "ceramide

6") (10.0 mg/kg) alone (Group 2), taxol, i.e. paclitaxel (3.0 mg/kg) alone (Group 3), oxaliplatin (2.5 mg/kg) alone (Group 4), cis-platinum (also referred to as "cisplatin") (2.5 mg/kg) alone (Group 5), or combinations of taxol and C<sub>6</sub>-ceramide (Group 6), oxaliplatin and C<sub>6</sub>-ceramide (Group 7), and cis-platinum and C<sub>6</sub>-ceramide (Group 8). The control group (Group 1) contained mice receiving no chemotherapeutic agent. The mice were treated 3 times per week for 4 weeks, and were observed for 6 weeks after commencing chemotherapy. The experimental results discussed below are those obtained with respect to Groups 1, 2, 5, and 8, even though data with respect to the remaining Groups are shown in the Exhibits annexed hereto.

7. Survival percentage rates among mice in Groups 1-8 were determined. As shown in **EXHIBIT B**, all mice in the control group (Group 1) died by the third week. All mice receiving C<sub>6</sub>-ceramide alone (Group 2) died by the fourth week. All mice receiving taxol alone (Group 3) died by the fourth week. In contrast, 60% of the mice receiving a combination of taxol and C<sub>6</sub>-ceramide (Group 6) were still alive as of the sixth week.
8. Mean survival times ("MST") among the mice in Groups 1-8 were determined. As shown in **EXHIBIT C**, the mice in the control group (Group 1) had a MST of approximately 17.8 days; the mice receiving C<sub>6</sub>-ceramide alone (Group 2) had a MST of approximately 20.8 days; the mice receiving taxol alone (Group 3) had a MST of approximately 23.0 days; and the mice receiving a combination of taxol and C<sub>6</sub>-ceramide (Group 6) had a MST of approximately 35.2 days.
9. Tumor volumes among the mice in Groups 1-8 were determined. As shown in **EXHIBIT D**, the mice in the control group (Group 1) had tumors with a mean tumor volume ("MTV") of approximately 1.56 cm<sup>3</sup>; the mice receiving C<sub>6</sub>-ceramide alone (Group 2) had

tumors with a MTV of approximately 1.69 cm<sup>3</sup>; the mice receiving taxol alone (Group 3) had tumors with a MTV of approximately 1.83 cm<sup>3</sup>; and the mice receiving a combination of taxol and C<sub>6</sub>-ceramide (Group 6) had tumors with a MTV of approximately 1.19 cm<sup>3</sup>.

10. The mean rate of tumor development ("MRTD"), which indicates the speed of tumor development, was measured among the mice in Groups 1-8 using the formula MTV/MST. As shown in **EXHIBIT E**, the mice in the control group (Group 1) had a MRTD of approximately 0.086 cm<sup>3</sup>/day; the mice receiving C<sub>6</sub>-ceramide alone (Group 2) had a MRTD of approximately 0.082 cm<sup>3</sup>/day; the mice receiving taxol alone (Group 3) had a MRTD of approximately 0.078 cm<sup>3</sup>/day; and the mice receiving a combination of taxol and C<sub>6</sub>-ceramide (Group 6) had a MRTD of approximately 0.035 cm<sup>3</sup>/day.
11. The mean weight of tumor ("MWT") among the mice in Groups 1-8 was determined. As shown in **EXHIBIT F**, the mice in the control group (Group 1) had a MWT of approximately 1.56 grams; the mice receiving C<sub>6</sub>-ceramide alone (Group 2) had a MWT of approximately 1.04 grams; the mice receiving taxol alone (Group 3) had a MWT of approximately 0.82 grams; and the mice receiving a combination of taxol and C<sub>6</sub>-ceramide (Group 6) had a MWT of approximately 1.26 grams.
12. Mean body weight ("MBW") was measured every week for the mice in Groups 1-8. As shown in **EXHIBIT G**, the mice in the control group (Group 1) had a MBW of approximately 17.2 grams; the mice receiving C<sub>6</sub>-ceramide alone (Group 2) had a MBW of approximately 17.0 grams; the mice receiving taxol alone (Group 3) had a MBW of approximately 17.4 grams; and the mice receiving a combination of taxol and C<sub>6</sub>-ceramide (Group 6) had a MBW of approximately 20.0 grams.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made herein on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the subject application or any patent issuing thereon.

Harold J. Wanebo  
Harold J. Wanebo, M.D.

8/12/08  
Date

## **EXHIBIT A**

Applicants: Harold J. Wanebo and Shashikant Mehta  
U.S. Serial No.: 09/287,884  
Filed: April 7, 1999

# **CURRICULUM VITAE**

**HAROLD JOSEPH WANEBO, M.D.**

## **PERSONAL INFORMATION**

Date of birth	February 12, 1935
Place of birth	Denver, Colorado
Citizenship	United States
Social Security Number	524-36-2906
Home Address	116 Poppasquash Road Bristol, Rhode Island 02809
Mailing Address	Department of Surgery Landmark Medical Center 206 Cass Avenue Woonsocket, Rhode Island 029895
Business Telephone Number	401/767-1595
Fax	401/767-1508
E- mail	hwanebo@rwmc.org

## **EDUCATION**

1953-1957	Regis College Denver, Colorado B.S. - Chemistry
1957-1961	University of Colorado Medical Center Denver, Colorado M.D.

## **CURRENT APPOINTMENT**

2006-	Director, Division Surgical Oncology Landmark Medical Center Woonsocket, RI
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## **POSTGRADUATE TRAINING**

Internship and Residency  
Medicine  
1961-1963

Cornell Medical Division  
Bellevue Hospital  
New York, New York

Surgical Residency  
1963-1965

University of California Medical Center  
San Francisco, California

Fellowship in Tumor Immunology  
1965-1967

Memorial Sloan-Kettering Cancer Center

Surgical Fellowship  
1967-1968

University of California Medical Center  
San Francisco, California

Chief Surgical Residency  
1968-1969

University of California Medical Center  
San Francisco, California

Surgical Oncology Fellowship  
1971-1972

Memorial Sloan-Kettering Cancer Center  
New York, New York

## **POSTGRADUATE HONORS AND AWARDS**

1969-1971

National Defense Service Medal, Bronze  
Star Medal, Vietnam Service Medal, RVN  
Campaign Medal, Army Commendation  
Medal with "V" Device

1974 -1977

Junior Faculty Clinical Fellowship Award  
American Cancer Society

1978-1983

Appointed as American Cancer Society  
Professor of Clinical Oncology (State of  
Virginia), University of Virginia  
Charlottesville, Virginia

November 13, 1997

Awarded for His Invaluable Contribution  
to the Progress of Surgery in Japan. The 59th  
Congress of the Japanese Society for Clinical  
Surgery

April 26, 1999

Distinguished Service Award - American Head  
and Neck Society, Annual Meeting, Palm Desert,  
California

## **MILITARY SERVICE**

1969-1971

Major - United States Army, Vietnam and  
U. S. Army Hospital, Fort Carson, Colorado

## **PROFESSIONAL LICENSES AND BOARD CERTIFICATION**

December 12, 1970  
1987

American Board of Surgery  
Rhode Island - MD 7200  
Also Licensed in California 1969, New  
York 1971, Virginia 1977

## **ACADEMIC APPOINTMENTS**

1988-

Professor of Surgery, Boston University  
School of Medicine, Boston, MA  
Adjunct Professor, Brown University  
School of Medicine, Providence, RI

1987-1998

Professor of Surgery  
Director - Division of Surgical Oncology  
Brown University School of Medicine  
Providence, Rhode Island

1977-1986

Consultant- Clinical Immunology Service  
Memorial Sloan-Kettering Cancer Center  
New York, New York

1977-1987

Professor of Surgery  
Chief - Division of Surgical Oncology  
University of Virginia Medical Center  
Charlottesville, Virginia

1977-1983

Associate Scientist  
Memorial Sloan-Kettering Cancer Center  
New York, New York

1975-1977

Assistant Professor of Surgery  
Cornell University Medical Center  
New York, New York

1973-1977

Associate  
Memorial Sloan-Kettering Cancer Center  
New York, New York

1973-1975

Instructor in Surgery  
Cornell University  
New York Hospital Medical Center

## **HOSPITAL APPOINTMENTS**

1987-2002

Chairman of Surgery  
Roger Williams Medical Center  
Providence, Rhode Island

1977-1987

Chief, Division of Surgical Oncology  
University of Virginia Medical Center  
Charlottesville, Virginia

1974-1977

Assistant Attending Surgeon  
Memorial Sloan-Kettering Cancer Center  
New York, New York

1973-1974

Clinical Assistant Attending Surgeon  
Memorial Sloan-Kettering Cancer Center  
New York, New York

## **HOSPITAL COMMITTEES**

### **ROGER WILLIAM'S MEDICAL CENTER**

1987-

Executive Committee

1987-

Quality Improvement Steering Committee

1987-

Cancer Committee

1987-

Chairman - Operating Room Committee

1987-

Joint Conference Committee

1987-

Tumor Board

1990-1996

Roger Williams Cancer Center  
Executive Committee

## **UNIVERSITY COMMITTEES**

1992-1996

Executive Committee - Brown University  
Cancer Center

1995-1996

Co-director, Division of Clinical Oncology,  
Brown University Cancer Center

1998-1996

Department of Surgery Promotions  
Committee and Surgical Chiefs Committee

## **MEMBERSHIP IN SOCIETIES**

1986-1989

National Cancer Institute  
Clinical Cancer Investigation Committee

1977-1987

Medical Society of Virginia  
Cancer Committee

1986-1988  
1998-

Society of Head and Neck Surgeons  
Chairman - Research Committee  
Education Committee  
Executive Committee  
Head and Neck Oncology Fellowship  
Joint Council Training Program  
Post Graduate Training Committee  
Research Committee

1998-  
1997-

1980-1986  
1992-1995  
1997-

Society of Surgical Oncology  
Chairman - Resident Award Committee  
Committee on Training  
Membership Committee

1985-

Southeastern Cancer Study Group  
Chairman - Gastrointestinal Committee

1985-1986

Mid-Atlantic Oncology Group  
Co-Director

1985-1995

American Cancer Society(National)  
Committee on Clinical Oncology Career  
Development Award and Clinical  
Oncology Fellowships

1980-1987	American Cancer Society(Virginia) Liaison Fellow - Commission on Cancer (Virginia)
1992-1995 1988-1996 1996-	American Cancer Society(Rhode Island) Member - Board of Governors Professional Education Committee Vice-President - Rhode Island Chapter of American Cancer Society
1981-1991	American College of Surgeons Member - Executive Committee Member - Commission on Cancer Education Committee Committee on Patient Care and Research
1985-1986	Chairman - Cancer Management Course
1980-1987	Liaison Fellow - Commission on Cancer (Virginia)
1983-1986	Colorectal Cancer Control Project of Virginia Co-Director National Surgical Adjuvant Breast and Bowel Project
1997-1999	Colorectal Disease Committee
1980-	National Institutes of Health Consultant - Ad Hoc Study Section Allergy and Infectious Diseases
1993-	Annals of Surgical Oncology Editorial Board - Head and Neck
1988-1992	Journal of Cancer Education
1995-	Journal of Surgical Association(R.O.C.) Taiwan, China International Advisor

1998-

Gastric Cancer  
Tokyo, Japan  
Associate Editor

Ad Hoc Reviewer for Cancer, Journal of Surgical Oncology, Annals of Surgery, American Journal of Surgery, Archive of Surgery, Oncology, World Journal of Surgery.

1997-2002

Advanced Training Council, The American  
Head and Neck Society

### **MEMBERSHIP IN PROFESSIONAL SOCIETIES**

American Association for Cancer Education  
American Association for Cancer Research  
American Association of Immunologists  
American Society of Clinical Oncology  
American Surgical Association  
Association of American Volunteer Physicians  
Medical Society of New York  
Medical Society of Rhode Island  
Medical Society of Virginia  
Naffziger Surgical Society (University of California, San Francisco)  
New England Surgical Society  
New York Academy of Science  
New York Surgical Society  
Society for Surgery of the Alimentary Tract  
American Society of Head and Neck Surgeons  
Society of University Surgeons  
Southeastern Surgical Congress  
Southern Surgical Association

### **PEER REVIEW JOURNAL PUBLICATIONS**

**HAROLD J. WANEBO, M.D.**

1. Wanebo HJ, Katsh S, Bromberger-Bamea B: Comparative activities of certain antihistamines on inhibition of isolated rabbit auricles. Arch Int Pharmacodyn Ther 37:116-120, 1962.

2. Wanebo HJ, Clarkson BD: Essential macroglobulinemia: Report of a case including immunofluorescent and electron microscopic studies. *Ann Intern Med* 62:1025-1045, 1965.
3. Graham WP, Galante M, Goldman L, Wanebo HJ: Complications of ileostomy. *Am J Surg* 110: 142-147, 1965.
4. Wanebo HJ, Webb E, Combs R: Diagnosis of acute abdominal diseases in paraplegic patients. *Calif Med* 103:193-197, 1965.
5. Wanebo HJ, Geller W, Gerold F: Extramedullary plasmacytoma of upper respiratory tract: Recurrence after latency of thirty-six years. *New York J Med* 66:1110-1113, 1966.
6. Wanebo HJ: Tuberculosis tenosynovitis in the patient with hyperuricemia. *Calif Med* 104:484-487, 1966.
7. Wanebo HJ, Schlessinger I, Tashima CK: Severe hypoglycemia associated with terminal lymphomas: Report of five cases. *Cancer* 19:1451-1458, 1966.
8. Wanebo HJ, Benua RS, Rawson RW: Neoplastic diseases and thyrotoxicosis. *Cancer* 19:1523-1526, 1966.
9. Wanebo HJ, Gallmeier WM, Boyse EA, Old U: Paraproteinemia and reticulum cell sarcoma in an inbred mouse strain. *Science* 154:901-903, 1966.
10. Wanebo HJ, Hunt TK, Mathewson C, Jr.: Rectal injuries. *J Trauma* 9:712-722, 1969.
11. De Tkaczewski LZ, Wanebo HJ: Electron microscopy of murine SJL-J disease. *Int J Cancer* 4:533-547, 1969.
12. Wanebo HJ, Rawson RW: Lupus erythematosus complicated by the Chiari-Frommel syndrome and autoimmune thyroidism. *Arch Intern Med* 124:619-622, 1969.
13. Wanebo HJ, Zipp PA, Kountz SL: Acceleration of reticulum cell sarcoma in SJL mice chronically treated with heterologous antilymphocyte serum. *Surg Forum* 20:120-122, 1969.
14. Carswell EA, Wanebo HJ, Old LJ, Boyse EA: Immunogenic properties of reticulum cell sarcomas of SJL-J mice. *JNCI* 44:1281-1288, 1970.
15. Hunt TK, Leeds FH, Wanebo HJ, Blaisdell FW: Arteriovenous fistulas of major vessels in the abdomen. *J Trauma* 11:483-493, 1971.
16. Wanebo HJ, Mathewson C, Connolly WB: Pseudo-obstruction of the colon. *Surg Gynecol Obstet* 133:44-48, 1971.

17. Wanebo HJ, Van Dyke J: The high velocity pulmonary injury: Relation to traumatic wet-lung syndrome. *Thorac Cardiovasc Surg* 64:537-550, 1972.
18. Wanebo HJ, Van Dyke J: High velocity pulmonary injury: Relation to traumatic wet-lung syndrome. *NY State J Med* 72:1728-1730, 1972.
19. Wanebo HJ, Shah J, Knapper W, Hajdu S, Booher R: Re-appraisal of surgical management of sarcoma of the buttock. *Cancer* 31:97-104, 1973.
20. Wanebo HJ, Huvos AG, Urban JA: Proceedings: Treatment of minimal breast cancer. *Cancer* 33:349- 357, 1974.
21. Wanebo HJ, Quan SH: Failures of electrocoagulation of primary carcinoma of the rectum. *Surg Gynec Obstet* 138:174-176, 1974.
22. Arlen M, Wanebo HJ, Gueffa O, Higinbotham N, Huvos A, Millar T: Osseous metastasis: Its relationship to primary carcinoma of the head and neck. *Am J Surg* 128:568-572, 1974.
23. Lundy J, Wanebo HJ, Pinsky C, Strong E, Oettgen H: Delayed hypersensitivity reactions in patients with squamous cell cancer of the head and neck. *Am J Surg* 128:530-533, 1974.
24. Tsakraklides V, Wanebo HJ, Steinberg SS, Steams M, Good RA: Prognostic evaluation of regional lymph node morphology in colorectal cancer. *Am J Surg* 129:174-180, 1975.
25. Wanebo HJ, Woodruff J, Former JG: Malignant melanoma of the extremities: A clinicopathologic study using levels of invasion (microstage). *Cancer* 35:666-676, 1975.
26. Wanebo HJ, Grimes OF: Cancer of the bile duct: The occult malignancy. *Am J Surg* 130:262-268, 1975.
27. Lundy J, Raaf JH, Deakins S, Wanebo HJ, Jacobs D, Stungdao L, Jacobwitz D, Spear C, Oettgen H: The acute and chronic effect of alcohol on the human immune system. *Surg Gynecol Obstet* 141:212-218, 1975.
28. Wanebo HJ, Former J, Woodruff J, MacLean B, Binkowski E: Selection of the optimum surgical treatment of Stage I melanoma by depth of microinvasion: Use of the combined microstage technique (Clark-Breslow). *Ann Surg* 182:302-315, 1975.
29. Wanebo HJ, Jun MY, Strong EW, Oettgen HJ: T-cell deficiency in patients with squamous cell cancer of the head and neck. *Am J Surg* 130:445-451, 1975.



30. Hirshaut Y, Pinsky C, Wanebo HJ, Oettgen H: Design of phase I trials of immunopotentiators for cancer therapy: Levamisole and *Corynebacterium parvum*. *Ann NY Acad Sci* 277:252-259, 1976.
31. Wanebo HJ, Martini N, Melamed M, Beattie EJ, Jr.: Pleural mesothelioma. *Cancer* 38:2481-2488, 1976.
32. Wanebo HJ, Rao B, Miyazawa N, Martini N, Middleman MP, Oettgen H, Beattie EJ, Jr.: Immune reactivity in primary carcinoma of the lung and its relation to prognosis. *J Thorac Cardiovasc Surg* 72:339-350, 1976.
33. Cunningham-Rundles S, Feller WF, Cunningham-Rundles A, Dupont B, O'Reilly R, Wanebo HJ, Good RA: Lymphocyte transformation in vitro to RII mouse milk and antigen among women with breast disease. *Cell Immunol* 25:322-327, 1976.
34. Wanebo HJ, Rosen PP, Thaler T, Urban JA, Oettgen HF: Immunobiology of operable breast cancer: An assessment of biologic risk by immunoparameters. *Ann Surg* 184:258-267, 1976.
35. Wanebo HJ, Kemeny M, Pinsky CM, Hirshaut Y, Oettgen H: Influence of poly (A)-poly (U) on immune response in cancer patients. *Ann NY Acad Sci* 277:288-298, 1976.
36. Teshima H, Wanebo HJ, Pinsky C, Gee T, Day NK: Circulating immune complexes detected by 125 I-Clq deviation test in sera of cancer patients. *J Clin Invest* 59:1134-1142, 1976.
37. Pinsky CM, Wanebo HJ, Mike V, Oettgen H: Delayed cutaneous hypersensitivity reactions and prognosis in patients with cancer. *Ann NY Acad Sci* 276:407-410, 1976.
38. Pinsky CM, Hirshaut Y, Wanebo HJ, Fortner J, Mike V, Schottenfield D, Oettgen H: Randomized trial of *Bacillus Calmette-Guerin* (percutaneous administration) as surgical adjuvant immunotherapy for patients with stage-II melanoma. *Ann NY Acad Sci* 277:187-194, 1976.
39. Delmonte L, Oettgen HF, Hirshaut Y, Pinsky CM, Wanebo HJ: *Corynebacterium parvum*. *Clin Bull* 6:31-34, 1976.
40. Khafagy N, Wanebo HJ, Alfieri A, Hahn EW: Effect of different cancer treatment methods on immunity to an antigenic transplantable murine fibrosarcoma (Meth A). *AJR* 128:1027-1029, 1977.
41. Rao B, Wanebo HJ, Ochoa M Jr., Lewis JL Jr., Oettgen HF: Intravenous *Corynebacterium parvum*: An adjunct to chemotherapy for resistant advanced ovarian cancer. *Cancer* 39:514-526, 1977.

42. Hilal EY, Wanebo HJ, Pinsky CM, Middleman P, Strong EW, Oettgen HF: Immunologic evaluation and prognosis in patients with head and neck cancer. *Am J Surg* 134:468-473, 1977.
43. Wanebo HJ: Lymph-node dissection in melanoma. (Letter to the Editor) *N Eng J Med* 298:222-223, 1978.
44. Wanebo HJ, Semoglou C, Attiyeh F, Steams MJ Jr.: Surgical management of patients with primary operable colorectal cancer and synchronous liver metastases. *Am J Surg* 135:81-85, 1978.
45. Wanebo HJ, Rao B, Pinsky CM, Hoffman RG, Steams M, Schwartz, MK, Oettgen HF: Preoperative carcinoembryonic antigen level as a prognostic indicator in colorectal cancer. *N Eng J Med* 299:448-451, 1978.
46. Hirshaut Y, Kesselheim H, Pinsky CM, Braun D, Wanebo HJ, Oettgen HF: Levamisole as an immunoadjuvant: Phase I study and application in breast cancer. *Cancer Treat Rep* 62:1693-1701, 1978.
47. Wanebo HJ, Thaler HT, Hansen JA, Rosen PP, Robbins GF, Urban JA, Oettgen HF, Good RA: Immunologic reactivity in patients with primary operable breast cancer. *Cancer* 41:84-94, 1978.
48. Wanebo HJ, Pinsky CM, Beattie EJ, Oettgen HF: Immunocompetence testing in patients with one of the four common operable cancers - a review. *Clin Bull* 8:15-22, 1978.
49. Wanebo HJ, Rao B, Pinsky CM, Hoffman RG, Steams M, Schwartz MK, Oettgen HF: Preoperative carcinoembryonic antigen level as a prognostic indicator in colorectal cancer. *N Eng J Med* 299:448-451, 1978.
50. Attiyeh FF, Wanebo HJ, Steams MW: Hepatic resection of metastasis from colorectal cancer. *Dis Colon Rectum* 21:160-162, 1978.
51. Wanebo HJ, Steams M, Schwartz MK: Use of CEA as an indicator of early recurrence and as a guide to a selected second-look procedure in patients with colorectal cancer. *Ann Surg* 188:481-493, 1978.
52. Krown SE, Hilal EY, Pinsky CM, Hirshaut Y, Wanebo HJ, Hansen JA, Huvos AG, Oettgen HF: Intralesional injection of the methanol extraction of residue of bacillus calmette-guerin(MER) into cutaneous metastases of malignant melanoma. *Cancer* 42:2648-2660, 1978.
53. Carey JT, Fracchia AA, Fotino M, Watson RC, Reich LC, Wanebo HJ: Immunology for advanced breast cancer. *Compr Ther* 4:65-73, 1978.

54. Wanebo HJ, Hilal EY, Pinsky CM, Strong DW, Mike V, Hirshaut Y, Oettgen HF: Randomized trial of levamisole in patients with squamous cancer of the head and neck. *Cancer Treat Rep* 62:1663-1669, 1978.
55. Wanebo HJ, Hilal EY, Strong EW, Pinsky CM, Mike V, Oettgen HF: Adjuvant trial of levamisole in patients with squamous cancer of the head and neck: A preliminary report. *Recent Results in Cancer Res* 68:324-333, 1978.
56. Wanebo HJ, Fukuda M, Tsuei L, Sarkar N, Ashikari H: The leukocyte migration inhibition response to certain breast cancer-related antigens (MCF-7 and MUMTV): Their potential as discriminants. *Surgery* 86:275-283, 1979.
57. Wanebo HJ: Immunobiology of head and neck cancer. Basic concepts. *Head Neck Surg* 2:42-55, 1979.
58. Unger SW, Bernhard MI, Pace R, Wanebo HJ: Alterations of monocyte function in neoplastic diseases. *Surg Forum* 30:142-144, 1979.
59. Forrest JB, Wanebo HJ: An unusual complication of central venous catheterization. *Va Med* 106:659, 1979.
60. McGovern FH, Estevez JM, Wanebo HJ: Papillary carcinoma in the thyroglossal tract. *Va Med* 106:151-153, 1979.
61. Wanebo HJ: Immunologic testing as a guide to cancer management. *Surg Clin North Am* 59:323-347, 1979.
62. Fukuda M, Wanebo HJ, Tsuei L, Sarkar NH: Leukocyte migration inhibition response to various antigen preparations of autologous and homologous breast cancer in patients with primary breast cancer. *J Natl Cancer Inst* 63:1161-1169, 1979.
63. Fukuda M, Wanebo HJ, Tsuei L, Ashikari R, Sarkar NH: Leukocyte migration inhibition response among breast cancer patients in response to various oncogenic viruses. *J Natl Cancer Inst* 64:431-437, 1980.
64. Bernhard MI, Pace RC, Unger SW, Wanebo HJ: The influence of incubation time and mitogen concentration on lymphocyte blastogenic response: Determination of conditions that maximize population differences. *J Immunol* 124:964-968, 1980.
65. Hirshaut Y, Pinsky CM, Frydecka I, Wanebo HJ, Passe S, Mike V, Oettgen HF: Effect of short-term levamisole therapy on delayed hypersensitivity. *Cancer* 45:362-366, 1980.
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127. Wanebo HJ, Begossi G, Levy A, Gustafson E, Belliveau J. Isolated chemotherapeutic perfusion as neoadjuvant therapy for advanced/unresectable pelvic malignancy. American Society of Clinical Oncology Gastrointestinal Cancers Symposium. January 22-24, 2004. San Francisco, CA
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130. Wanebo HJ, Begossi G, Levy A, Gustavson E, Belliveau J. Isolated chemotherapeutic perfusion as neoadjuvant therapy for advanced/unresectable pelvic malignancy. Society of Surgical Oncology, March 18-21, 2004. New York, NY
131. Wanebo HJ, Ponomarenko I, Begossi G, Antoniuk P, Vezeridis M, Wroblewski D, Koness RJ. Abdominal sacral resection improves both overall and disease-free survival in selected patients with locally advanced or recurrent rectal cancer. Society of Surgical Oncology, March 18-21, 2004. New York, NY.
132. Shraye D, Essis D, Mehta S, Wanebo H. Ceramide, a mediator of apoptosis, synergizes with paclitaxel to induce regression of the L3.6 human pancreatic carcinoma implanted in SCID mice. Journal of Clinical Oncology, ASCO Annual Meeting Proceedings, July 2004.
133. Nadeem A, Desai S, Chougule P, Wanebo H, Ruhl C, Joyce D, Tarro J, Kenendy T, Ready N. Decreased distant recurrence and preserved local control using dose dense induction weekly paclitaxel (P) and carboplatin (C) followed by concurrent paclitaxel, carboplatin and radiotherapy (CRT) in locally advanced head and neck squamous cell cancer (HN-SCC). Journal of Clinical Oncology, ASCO Annual Meeting Proceedings, July 2004.
134. Wanebo HJ, Chougule P, Ready N, Kones RJ, McRae R, Nigri P, Radie-Keane K, Rathore R, Kennedy T. Preoperative chemoradiation directly by primary site rebiopsy in stage III/IV squamous head and neck cancer is associated with high rate of local regional control, but is still plagued by long-term distant failure. Journal of Clinical Oncology, 2004 ASCO Annual Meeting Proceedings, July 2004.
135. Rathore R, Chougule P, Wanebo H, Nadeem A, Radie-Keane K, Sikov W, Nigri P, Kenendy T, Ready N. Phase I/II study of induction weekly paclitaxel, ifosfamide and carboplatin (PIC) followed by chemoradiotherapy (CRT) in advanced head and neck squamous cell cancers (HN-SCC). Journal of Clinical Oncology, 2004 ASCO Annual Meeting Proceedings, July 2004.
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137. Shraye D, Essis D, Mehta S, Wanebo H. Ceramide, a mediator of apoptosis, synergizes with paclitaxel to induce regression of the L3.6 human pancreatic

carcinoma implanted in SCID mice. *Journal of Clinical Oncology*, 2004 ASCO Annual Meeting Proceedings (Post-Meeting Edition). Vol 22, No 14S (July 15 Supplement), 2004:2135.

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139. Wanebo HJ, Chougule P, Ready N, Koness RJ, McRae R, Nigri P, Radie-Keane K, Rathore R, Kennedy T. Preoperative chemoradiation directed by primary site rebiopsy in stage III/IV squamous head and neck cancer is associated with high rate of local regional control, but is still plagued by long-term distant failure. *Journal of Clinical Oncology*, 2004 ASCO Annual Meeting Proceedings (Post-Meeting Edition). Vol 22, No 14S (July 15 Supplement), 2004: 5549
140. Rathore R, Chougule P, Wanebo HJ, Nadeem A, Radie-Keane K, Sikove W, Negri P, Kennedy T, Ready N. *Journal of Clinical Oncology*, 2004 ASCO Annual Meeting Proceedings (Post-Meeting Edition). Vol 22, No 14S (July 15 Supplement), 2004:5602
141. Chauhan B, Wanebo HJ, Rathore R, Chougule P, Kennedy T, Ready N. *Journal of Clinical Oncology*, 2004 ASCO Annual Meeting Proceedings (Post-Meeting Edition). Vol 22, No 14S (July 15 Supplement), 2004:5601
142. Ready N, Aronson F, Wanebo HJ, Kennedy T. A Low Rate of Central Nervous System (CNS) Progression in a Phase II Trial of Outpatient Chemobiologic Therapy with Cisplatin, Temozolomide, Interleukin-2 (IL-2) and Interferon alfa 2-B (IFN) for Metastatic Malignant Melanoma. Submitted for Publication to the *American Journal of Clinical Oncology*
144. Safran H, Suntharalingam M, Wanebo H, Ng T, Krasna M, Doyle L, Benton D, Daly B, Spector J, Dopetrillo T. Cetuximab, paclitaxel, carboplatin, and radiation for esophageal and gastric cancer. *Proceedings (Post-Meeting Edition) ASCO Gastrointestinal Cancer Symposium*, January, 2006 p115.
145. Wanebo HJ, DiSiena M, Begossi G, Stager S, Belliveau, Gustafson E. Isolated chemotherapeutic perfusion of pelvis as neoadjuvant or palliative therapy for



Advanced cancer of the rectum or anorectum. Proceedings (Post-Meeting Edition)  
ASCO Gastrointestinal Cancer Symposium, January 2006, p263.

146. Shraye D, Resnick M, Wanebo H. The apoptosis signal ceramide (C6) synergizes the anti-tumor effects of paclitaxel, oxaliplatin and cisplatin on the growth of pancreatic cancer in scid mice L3.6. Presented at the Glycolipid and Sphingolipid Biology Gordon Conference, January, 2006.

## **PRESENTATIONS - HAROLD J. WANEBO, M.D.**

### **1977 PRESENTATIONS**

- February, 1977      American Society of Contemporary Medicine in Surgery, Miami, FL, Presentation - "An Immunologic Approach to the Treatment of Advanced Breast Cancer"
- October 6-10, 1977      Invited Speaker - Immuno-competence and Prognosis Conference, Ulm, West Germany, Presentation - "Relation of Immune Competence of Prognosis in Patients with Solid Tumors"
- December 3, 1977      Anatomica, Pathologica, Oncologica and Cytologica, Tumor Institute, Milan Italy, Invited Speaker - "Relevance of Immune System to Head and Neck Cancer"
- December 6, 1977      Surgical Grand Rounds, Roanoke, Virginia, Presentation - "CEA-directed Second-look Surgery"

### **1978 PRESENTATIONS**

- February 21, 1978      Southeastern Surgical Conference, Presentation - "Surgical Pathology of Recurrent Rectal Cancer"; Moderated Panel - "Breast Cancer Update"
- March 17-18, 1978      Invited Speaker - Second Annual Spring Oncology Seminar, Presentations - "Breast Cancer - Surgical Management"; "Colon Cancer - What's New"

- April, 1978 American Surgical Association, Presentation - "CEA Directed Second-look Surgery in Colorectal Cancer"
- April 23, 1978 Invited Speaker - Air Force Surgical Society, Biloxi, MI, Presentation - "Management of Melanoma"
- June 22, 1978 Invited Speaker - Immunotherapy Trials in Cancer Meeting, Dr. George Mathe, Paris, France, Presentation - "Lavamisole Trial in Head and Neck Cancer Patients"
- September 11, 1978 Invited Participant - Immunodiagnosis Workshop, National Cancer Institute, Bethesda, MD
- September 18, 1978 Invited Speaker - Lurleen Welfare Cancer Center, University of Alabama Medical Center, Presentation - "Surgical Management of Recurrent Colorectal Cancer"
- October 18, 1978 Invited Speaker - American College of Surgeons, Presentation - "Anorectal Melanoma"

#### **1979 PRESENTATIONS**

- January 19, 1979 Invited Speaker and Visiting Professor - National Cancer Institute, Bethesda, MD, Presentation - "Treatment of Recurrent Colorectal Cancer"
- February 8-9, 1979 Visiting Professor, Eastern Virginia Medical School, Norfolk, VA, Presentations - "Management of Malignant Melanoma"; "Management of Sarcoma"
- February 15, 1979 Society of University Surgeons, Presentation - "LMIT Responses to Putative Tumor Antigens in Breast Cancer Patients"
- May 14, 1979 American Society for Clinical Oncology, American Association for Cancer Research, Presentation - "Monocyte Function in Cancer Patients"
- October, 1979 American College of Surgeons, Presentation - "LMIT Responses to MTV in Breast Cancer Patients"
- October 9-11, 1979 NIH Study Section, Allergy and Immunology, AD Hoc Committee

December 7-8, 1979 Visiting Professor, University of Oregon, Oncology Symposium, Presentation - "Melanoma"

### **1980 PRESENTATIONS**

January 25, 1980 Invited Speaker, Surgical Grand Rounds, Roanoke Memorial Hospital, Roanoke, VA, Presentation - "New Advances in Colorectal Cancer"

March 28, 1980 Invited Speaker, Immunopharmacology of Radiation Meetings, Dr. Serou, Montpellier, France, Presentation - "Immune effects of Radiation in Head and Neck Cancer and Colon Cancer"

May, 1980 American Society for Clinical Oncology, American Association for Cancer Research, Presentation - "Monocyte Function in Cancer Patients"

May 11, 1980 Society for Surgical Oncology, Presentation - "Epidermoid Cancer of Anorectum"

September, 1980 Invited Speaker, West Virginia Medical School, Presentations - "Surgical Management of Hyperthyroidism"; "Management of Thyroid Cancer"

November 7, 1980 NIH Site Visit Team, UCLA Oncology Program (Dr. Morton), Los Angeles, CA

### **1981 PRESENTATIONS**

March 9, 1981 Head and Neck Society Meetings, Presentation - "Thyroid Cancer"

April 27, 1981 American Society for Clinical Oncology, American Association for Cancer Research, Presentation - "Fine Needle Aspiration Cytology versus Tru-cut Biopsy in the Diagnosis of Tumors"

June 4, 1981 Visiting Professor, University of Connecticut, Presentation - "CEA Directed Second-look Surgery"

June 6, 1981 Invited Speaker, West Virginia Surgical Society, Charleston, WV, Presentation - "Use of CEA in Colorectal Cancer"

June 16, 1981 Consultant, NCI, Site Visit, University of Minnesota, Colorectal Cancer Screening Program, Dr. Gilbertson

August 8, 1981 CEA Consensus Meeting, National Cancer Institute, Bethesda, MD, Presentation - "CEA as a Prognostic Determinant"

- October, 1981 American College of Surgeons, Presentation - "Fine Needle Aspiration Cytology Versus Tru-cut Biopsy in the Diagnosis of Tumors"
- November 5, 1981 Ad Hoc Committee, NIH Study Section, Allergy and Immunology, Chairman, Dr. Robert Schwartz
- December 3, 1981 Visiting Professor, Department of Radiation Therapy, Barnes Hospital, Washington University, St. Louis, MO, Presentation - "Management of Hepatoma"
- December 6, 1981 Southern Surgical Association, Presentation - "Gallbladder Cancer"

### **1982 PRESENTATIONS**

- January 18, 1982 Tidewater Cancer Conference, Norfolk, VA, Presentation - "Management of Sarcomas"
- March 16, 1982 American Radium Society, San Antonio, TX, Presentation - "Use of Abdominal Sacral Resection in the Management of Posterior Pelvic Malignancy"
- March 19, 1982 Conference on Melanoma, Boca Raton Medical Society, Boca Raton, FL, Presentation - "Surgical Management of Melanoma"
- April 6, 1982 Visiting Professor, Cincinnati Surgical Society, University of Cincinnati, Cincinnati, OH, Presentation - "Management of Liver Tumors"
- April 19, 1982 Society of Surgical Oncologists/Society of Head and Neck Surgeons, Marco Island, FL, Presentation - "Indomethacin Sensitive Suppressor Cells in Head and Neck Cancer Patients"
- April 24, 1982 American Society for Clinical Oncology/American Association for Cancer Research, St. Louis, MO, Presentation - "Effect of Cimetidine on Lymphocyte Function in Cancer Patients"
- May 17, 1982 Cancer Symposium, University of Maryland Cancer Center, Baltimore, MD, Presentation "Relationship of Immune Parameters to Prognosis in Cancer Patients"
- June 16-20, 1982 Invited Speaker, Conference on Hepatic and Biliary Tract Cancer, Rome, Italy, Presentation - "Surgical Management of Hepatic Metastases from Colorectal Cancer"

- September 9, 1982 International Cancer Conference, Seattle, WA, Chaired Session - "New Advances in Oncologic Surgery"; Presentation - "Resection of Posterior Pelvic Malignancy"
- October 21, 1982 American College of Surgeons, Poster Presentation - "Techniques of Abdominal Sacral Resection", Presentation for Cancer Management Course - "Management of Nodes in Malignant Melanoma"

### **1983 PRESENTATIONS**

- January 12, 1983 Invited Speaker, American Cancer Society, Denver, CO, Presentation - "Adult Tissue Sarcomas"
- March 4, 1983 Visiting Professor, University of Louisville, Louisville, KY, Presentations - "Surgical Management of Soft-part Sarcomas"; "Prognostic and Therapeutic Update for the Management of Malignant Melanoma"
- March 23, 1983 Invited Speaker, Good Samaritan Hospital, Vincennes, IN, Presentation - "Management of Liver Metastases"
- May 2, 1983 Society of Surgical Oncology, Denver, CO, Abstract Presentations - "An Antitumor Factor in the Alpha Globulin Region of Normal Human Sera"; "Surgical Pathologic Considerations in the Proper Staging of Soft-part Sarcomas of the Extremities"
- May 23-27, 1983 American Society for Clinical Oncology/American Association for Cancer Research, San Diego, CA, Presentations - "The Use of Intra-arterial Chemotherapy for the Treatment of Melanoma of the Extremities"; "An Antitumor Factor in the Alpha Globulin Region of Normal Human Sera"
- August 6, 1983 Invited Speaker, Indiana University, Bloomington, IN, Presentations - "Management of Locally Recurrent Colon Cancer"; Utility of Operations Design to Preserve Anal Functions Using the Management of Malignant Lesions of the Distal Colon"
- September 21, 1983 Symposium on Malignant Neoplasms, Washington, DC, Presentation - "Reoperative Surgery for Perineal and Pelvic Recurrences: When is a Second-look Operation Necessary?"
- October 14, 1983 Invited Speaker, University of Maryland, Baltimore, MD, Presentation - "Pelvic Relapse of Abdominal Malignancy"

November 10, 1983    Invited Speaker, Detroit Academy of Surgery, Detroit, MI, Presentations  
"Surgical Management of Liver Metastases"; "Immune Evaluation of  
Cancer Patients: Implications for Clinical Management"

### **1984 PRESENTATIONS**

February 2, 1984    Invited Speaker, Washington and Lee University, Lexington, VA,  
Presentation - "Colorectal Cancer"

March 1-3, 1984    Invited Speaker, New England Deaconess Hospital, Boston, MA,  
Presentation - "Regional Infusion/Perfusion of Extremity and Pelvic  
Malignancy"

March 16-17, 1984    Invited Speaker, Oncology Symposium on Gastric, Pancreatic and  
Colonic Cancer, Miami FL, Presentation - "Surgical Treatment of GI  
Malignancies"

March 19, 1984    Invited Speaker, James Madison University, Harrisburg, VA,  
Presentation - "Colorectal Cancer"

April 10, 1984    Invited Speaker, St. Louis Community Clinical Oncology Program (Dr.  
Burt Needles), St. Louis, MO, Presentation - "What's New in  
Oncology?"

May 11, 1984    Invited Speaker, Skin Cancer Symposium, Chesapeake Memorial  
Hospital, Presentation - "Sarcoma of the Skin and Cutaneous Tissues"

### **1985 PRESENTATIONS**

April 17-20, 1985    Invited Presentations, The University General Hospital, Oncology  
Course, Director Hector Rodriquez, M.D., Mexico City, Mexico -  
"Advances in Head and Neck Surgery: Modified Radical Neck  
Dissection"; "Principles in Surgical Treatment of Soft Tissue Sarcomas:  
New Tendencies"; "New Concepts in Multidisciplinary Treatment on  
Breast Cancer Stages III and IV"; "Limb Conservation in the Surgical  
Treatment of Osteogenic Sarcoma"

May 3-5, 1985	International Melanoma Conference, Invited Presentations, Venice, Italy, "Chemotherapy and Immunotherapy of Metastatic Melanoma"; "Management of Thin Melanomas"
May 6-8, 1985	Society of Head and Neck Surgeons, Puerto Rico, Presentation - "Interleukin 2 Production by Head and Neck Cancer Patients"
May 19-21, 1985	American Society of Clinical Oncology, Houston, TX, Presentation - "Augmentation of Surgical Results for High Grade Extremity Sarcomas by Intraarterial Adriamycin and Radiation"
May 21-24, 1985	American Association for Cancer Research, Houston, TX, Presentation - "Interleukin 2 Production by Peripheral Blood Leukocytes in Cancer Patients"
June 18, 1985	Rockingham Memorial Hospital, Harrisburg, VA, Continuing Medical Education Program, Presentation - "Management of Malignant Melanoma"
June 24-26, 1985	University of Minnesota, Minneapolis, MN, 49th Annual Continuing Education Course in Surgery, Presentations - "Fine Needle Aspiration of Breast Cancer; "Risk Factors in Breast Cancer"
July 10-27, 1985	European-American Surgery Seminar, Austria, Lectures included Melanoma, Colorectal Cancer, Breast Cancer, Gallbladder Cancer, Sarcoma, Management of Liver Metastases
August, 1985	Visiting Professor, Eastern Virginia Medical School, Norfolk, VA, Presentation - "Management of Liver Metastases", Conducted Resident and Teaching Rounds
Oct 12-13, 1985	Society of Head and Neck Surgeons, Chicago, IL, Conducted Head and Neck Surgery Workshop
Oct 13-18, 1985	American College of Surgeons, Clinical Congress, Chicago, IL, Invited Presentations to Post Graduate Course - "Gallbladder Cancer"; "Recurrent Colorectal Cancer"; Movie Discussion - "Melanoma Management"; Presentation of Movie "Giant Cell Tumor of the Sacrum"
Nov 13-15, 1985	American Association for Cancer Education, Inc., San Francisco, CA, Presentation - "Screening for Colorectal Cancer"
November 25, 1985	James Madison University, Harrisburg, PA, Presentation - "Colorectal Cancer"

Dec 12-13, 1985 Visiting Professor, University of Cincinnati, Cincinnati, OH, Oncology Series, Presentation - "Resection of Hepatic Tumors"; Discussion - Grand Rounds - "Bile Duct Cancer"

### **1986 PRESENTATIONS**

January 11, 1986 Visiting Professor, University of Kansas, Kansas City, KS, Presentation - "Management of Difficult Problems in Colorectal Cancer"

February 21, 1986 American College of Surgeons, Puerto Rico Chapter, Presentation - "Management of Recurrent Colorectal Cancer"

April 2, 1986 University of Illinois, Chicago, IL, Presentation - "New Approaches to the Surgical Management of Malignant Disease"

April 3-5, 1986 American College of Surgeons, Cancer Management Course, San Diego, CA, Presentation - "Gastrointestinal Cancer Case Problems"

April 16-17, 1986 Federation of American Societies for Experimental Biology, St. Louis, MO, Presentation - "Use of IL2 to Augment the Lymphoproliferative Response to Weak Antigens"

April 25-27, 1986 Virginia Surgical Society, Hot Springs, VA, Presentation - "Resection of Liver Metastases"

April 30, 1986 American College of Surgeons, Pittsburgh, PA, Presentation - "The Use of Carcinoembryonic Antigens (CEA) in the Management of Colorectal Cancer"

May 4-6, 1986 American Society of Clinical Oncology, Los Angeles, CA, Presentation - "Prospective Monitoring Trial for Colorectal Cancer after Surgical Resection"

May 7-10, 1986 Society of Head and Neck Surgery, Colorado Springs, CO, Presentation - "Surgical Management of Vascular Malformations of the Head and Neck"

May 11-14, 1986 Society of Surgical Oncology, Washington, DC, Presentations - "A Blueprint for Risk Reduction of Colorectal Cancer Through Screening"; "Preoperative Irradiation for Rectal Cancer"; "Value of Interval Change in Mammographic Surveillance for Breast Cancer" - Posters "Enigmas of



- Head and Neck Melanoma"; "Major Pelvic Resections"; "Combined Therapy for Extremity Sarcomas"
- May 17, 1986 American Cancer Society, Beckley, WV, Presentation - "Colorectal Cancer"
- May 21-23, 1986 Invited Guest, Ogden Surgical Society, Ogden, UT, Presentations - "Fine Needle Aspiration Cytology in Lieu of Open Biopsy and Contralateral Biopsy - Breast Cancer"; "Sphincter Saving Surgery for Rectal Cancer"
- June 5, 1986 American Cancer Society, Norfolk, VA, Presentation - "Screening for Colorectal Cancer by Primary Care Physicians"
- June 9-13, 1986 First International Congress on Hepaticopancreatobiliary Cancer, Lund, Sweden, Presentations - "Hepatoma in Women: Role of Contraceptives"; "Infusional Chemotherapy for Metastatic-Colorectal Cancer to the Liver"
- June 27, 1986 American College of Surgeons, Cancer Management Course, Charlottesville, VA, Presentation - "Gastrointestinal Cancer"
- September 10, 1986 Seminar, Dayton, OH - "Aspiration versus Needle Biopsy of Breast Masses"; "Conservative Surgery for Early Breast Cancers"
- Sept 12-13, 1986 American College of Surgeons, Cancer Management Course, Presentations - 1. "Gastrointestinal Cancer"; 2. "Patient Management Problems"
- Sept 20, 1986 Surgical Grand Rounds, University of Virginia Medical Center, Charlottesville, VA, Presentation - "Conservation Surgery for Breast Cancer"

### **1987 PRESENTATIONS**

- Apr 25-30, 1987 Society of Surgical Oncology, London, England, Presentation - "Pelvic Resection for Tumors of Musculoskeletal Pelvis"; Poster - "Head and Neck Melanoma"
- May 1, 1987 Virginia Surgical Society, Williamsburg, VA, Presentation - "Selecting Therapies for Metastatic Liver Tumors"
- May 14, 1987 Society for Surgery of the Alimentary Tract, Presentation - "Gastric Lymphoma"
- May 17, 1987 American Society for Clinical Oncology, Atlanta, GA, Presentation - "Local Tumor Recurrence: A Consequence of Wound Healing"

- May 21, 1987 American Association for Cancer Research, Atlanta, GA, Presentation - "Isolation and Purification of the Antitumor Factor Normal Human Globulin (NHG)"
- Sept 10-12, 1987 2nd International Head and Neck Research Conference, Presentation - "Impaired Lymphocyte Function by Serum from Head and Neck Cancer Patients"; also moderated - Immunology Session - "IL2 Effects in Head and Neck Cancer"
- October 8, 1987 International Symposium on Sarcomas, Tampa, FL, Presentation - "Use of Fine Needle Aspiration Cytology for Sarcomas"
- Oct 13-15, 1987 Director of Head and Neck Surgery Workshop, University of California, San Francisco, CA
- October 15, 1987 American College of Surgeons, San Francisco, CA, Moderator Post Graduate Cancer Course - "Resection of Hepatic Metastases"; Presented movie - "Surgical Approach to Extensive Malignant Schwannoma of the Retroperitoneum"
- October, 1987 George Washington University Medical Center, Washington, D.C., Presentation - "Malignant Melanoma"

### **1988 PRESENTATIONS**

- February 1, 1988 Invited Presentation, Southeastern Surgical Congress, Buena Vista, FL, Symposium, Presentations - "Endocrine Tumors"; "Thyroid Cancer"
- April 28, 1988 Visiting Professor, Ellis Fischel Hospital, Presentation - "CEA Second-look Surgery"
- May 10, 1988 Visiting Professor, Evanston Hospital, Northwestern University, Evanston, IL, Presentation - "Abdominal Sacral Resection for Recurrent Rectal Cancer"
- May 22-25, 1988 Society of Surgical Oncology, Society of Head and Neck Surgeons, American Society of Clinical Oncology, American Association for Cancer Research, New Orleans, LA, Presentations - "Role of Limb Salvage Surgery and Chemotherapy in the Management of Extremity Sarcomas"; "Rational for Immune Restoration with IL2 in Patients with SCC of the Head and Neck"
- Sept 10, 1988 American College of Surgeons, Cancer Management Course, Newport, RI, Case Presentation - "Surgical Oncology"

- Oct 23-24, 1988 Co-Director, Head and Neck Surgery Workshop, Chicago, IL, Moderator of Session - "Thyroid and Parathyroid Cancer"
- Oct 24-28, 1988 American College of Surgeons, Chicago, IL, Presentations - "Prospective Monitoring Trial for Colorectal Cancer After Surgical Resection"; "Present Status and Clinical Application of TNF and Other Interleukin"; Also Moderated Session of Clinical Basic Science Problems in Surgery - "New Immunologic Approaches to the Control of Cancer"
- Nov 18-19, 1988 American College of Surgeons, Cancer Management Course, Sacramento, CA, Presented - 1. "Case Presentation Problem"; 2. "Skin Cancer and Melanoma"

### **1989 PRESENTATIONS**

- January 24, 1989 Head and Neck Oncology Series, Rhode Island Hospital, Providence, RI Presentation - "Head and Neck Melanomas"
- Feb 23-24, 1989 Pharmacology Symposium, San Diego, CA, Presentation - "Tumor Necrosis Factor"
- March 15, 1989 Plastic Surgery Conference, Rhode Island Hospital, Providence, RI, Presentation - "Head and Neck Melanoma"
- March 23, 1989 Newport Naval Hospital, Newport, RI, Presentation - "Liver Tumors"
- March 23, 1989 Roger Williams General Hospital, Providence, RI, Presentation - "Breast Cancer"
- May 21-23, 1989 Society of Surgical Oncology, Presentation - "Pre-Operative Chemotherapy and Radiation for Extremity Sarcomas: Tri Centre Study"
- May 21-23, 1989 American Society for Clinical Oncology, San Francisco, CA, Presentation - "Role of Surgery - Metastatic Melanoma"
- May 21-24, 1989 Society of Head and Neck Surgeons, Presentation - "Potential of IL-2 as an Immunoadjuvant for Head Neck Cancer"
- May 24-27, 1989 American Association for Cancer Research, San Francisco, CA, Presentation - "Further Purification of NHG: A Serum-Derived Antitumor Factor"
- September 9, 1989 Northern Virginia Cancer Center Symposium, Presentation - "Role of the Surgical Oncologist in the Modern Cancer Center"

- Sept 13-14, 1989 International Society of Surgery, 33rd World Congress, Invited Presentations - "Head and Neck Sarcomas - Report of the Head and Neck Sarcoma Registry"; "A Rationale for Treatment of Head and Neck Melanoma Based on Clinical Pathologic Risk Factors and Lymphoscintigraphy"
- September 30, 1989 Baystate Medical Center, Department of Surgery, Springfield, MA
- Oct 14-18, 1989 American College of Surgeons, Atlanta, GA, Moderator: Postgraduate Course - "Endocrine Tumors and Tumors of the Head and Neck"; "Prognostic and Therapeutic Considerations in the Management Symposium: Patient Care Evaluation Survey on Stomach Cancer"; Movie Presentation - "Composite Resection of Femur and Anterior Compartment for Extensive Sarcoma of Thigh: Reconstruction by a Hip-Knee Prosthesis"; "Extended Resection of Lumbosacral Osteosarcoma (L4, 5, S1-5) with Immediate Reconstruction by a Lumbosacral Allograft"
- Nov 10-12, 1989 New England Cancer Society, Newport, RI, Head and Neck Symposium: Surgical Aspects
- Nov 30-Dec 1, 1989 Clinical Oncological Society of Australia, Inc., Tripartite Scientific Meeting on Cancer Management, Perth, Australia, Presentation - "Surgical Management of Metastatic Melanoma"

### **1990 PRESENTATIONS**

- Feb 13-14, 1990 Calgary Society of Surgeons, Presentations - "Fine Needle Aspiration in the Management of Breast Lumps"; Foothills Hospital, General Surgery Rounds - "Limb Salvage Surgery for Sarcoma"; Gadeski Visiting Professor - Presentation - "New Frontiers in Melanoma Treatment"
- March 30, 1990 New Techniques in Liver Surgery, Brown University, Course Director, Presentation - "Surgical Anatomy of the Liver"
- July 24-26, 1990 The Second Annual Queen's Cancer Institute Symposium Gastrointestinal Malignancies, Honolulu, HI, Presentations - "Early

- Detection of Colorectal Cancer"; "Sphincter Preservation in the Management of Anal and Rectal Carcinoma"
- August 6, 1990      Laparoscopic Cholecystectomy Course, Brown University, Providence, RI, Course Director
- Sept 22-29, 1990      Gastrointestinal Cancer Course, Bordeaux, France, Presentations - "Gastric Cancer: Chemotherapy"; "Pancreatic Cancer: Surgical Approach"
- Nov 9-16, 1990      XVII Panhellenic Surgical Congress, Athens, Greece, Presentations - "Management of Gastric Cancer"; "CEA Second-look Surgery"
- Nov 22-23, 1990      The Japan Society of Colo-Proctology, Tokyo, Japan, Presentation - "Surgical Treatment of Recurrent Tumor After Colo-rectal Cancer Operation"

### **1991 PRESENTATIONS**

- Feb 28-March 2, 1991 American College of Surgeons, Orlando, FL, Presentation - "Screening and Early Detection of Colorectal Cancer: An Opportunity to Enhance the Primary Cure Rate"
- March 24-27, 1991      Society of Surgical Oncologists, Presentation - "Screening for Colorectal Cancer - Results of the Virginia Study"
- May 1-4, 1991      Society of Head and Neck Surgeons, Maui, HI, Presentations - "Use of Microstage and Lymphoscintigram in Selecting Surgical Treatment for Head and Neck Melanoma"; "Management of Cervical Nodes in Thyroid Cancer"
- May 19-21, 1991      American Society of Clinical Oncologists, Houston, TX, Poster Session - "Integrated Modality Protocol for Carcinoma of the Pancreas: Pilot Program"; "Isolated Pelvic Perfusion in a Canine Model: Patient Treatment Considerations"; and Differential Cytokine Effects on LAK Cell Lysis: Induction of Target Cell Resistance by Interferon Alpha (IFN  $\alpha$ )"
- May 22-24, 1991      American Association of Cancer Research, Houston, TX, Poster Sessions "Human B Cell Maturation Involves Distinct Proliferation and Differentiative Cytokine Signals"; and "Formalinized Extracellular Antigens of B-16 Melanoma are Effective Antitumore Vaccines"

- June 17-20, 1991 Conference on Regional Therapy, Rosenheim, Germany, Presentation - "Pelvic Resection for Advanced Cancer"
- Oct 21-24, 1991 American College of Surgeons, Presentation - "Pelvic Exenteration"; and "Surgical Management of Advanced Pelvic Cancer"
- Dec 1-4, 1991 Southern Surgical Society, Homestead, WV, Presentation - "Resection of Posterior Pelvic Malignancy"
- Dec 5, 1991 The Cancer Institute, Washing Hospital Center, Washington, D.C., Presentation - "Composite Resection for Intra-Pelvic and Sacral Malignancy"

### **1992 PRESENTATIONS**

- February 27, 1992 Grand Rounds, St. Mary's Hospital, Waterbury, CT, Presentation - "Management of Recurrent Rectal Cancer"
- Feb 28-29, 1992 Advanced Laparoscopy Course, Brown University, Providence, RI Course Director
- April 3-5, 1992 General Surgery Update, Hilton Head Island, SC, Presentations - "Screening and Early Detection/Colorectal Cancer"; "Second Look Surgery/Colorectal Cancer"; "Melanoma Update-1992"
- May 17-20, 1992 American Society of Clinical Oncology, San Diego, CA, Poster Session - "Survey of Patterns of Care for Gastric Cancer in the United States"
- May 20-23, 1992 American Association for Cancer Research, San Diego, CA, Poster Sessions - "Localized Pelvic Profusion with Charcoal Hemofiltration of 5FU and Cisplatin in the Canine Model: Potential for Selective Therapy of Pelvic Malignancy"; "Breast Cancer Risk in Women Attending a Breast Care Program"; "B700 antigen in the Immunodominant Form of an Anti-murine Melanoma Vaccine Prepared from Formalin-fixed Culture Supernatants"; "Polyclonal Antibodies to Formalinized Extracellular Antigens of B16-F10 Melanoma (FECA) Inhibit DNA Synthesis and React with Surface Antigens of B16-F10 Murine Melanoma Cells"
- May 28, 1992 University of Pittsburgh, Pittsburgh, PA - Joint Training Council Site Visit

- July 26, 1992 Third International Conference on Head and Neck Cancer, San Francisco, CA, Panel Presentations - "Sarcomas of the Head and Neck"; "Achieving High Complete Response Rates and Increased 5-year Survival"; "The Contribution of Serum Inhibiting Factors and Immune Cellular Defects to the Depressed Cell Medicated Immunity in Head and Neck Cancer Patients"
- Aug 30-Sept 2, 1992 First International Conference on Hepatobiliary Tumours, Milan, Italy, Presentation - "Surgical Management of Carcinoma of the Gallbladder"
- Sept 17-19, 1992 The Mid-Atlantic Oncology Program, Advances in Gastrointestinal Cancer, Presentation - "Preoperative Chemoradiotherapy for Pancreatic Cancer"
- Oct 30-31, 1992 American Cancer Society, Workshop on the Pretreatment Diagnostic Management of Recurrent Disease, San Francisco, CA, Presentation - "Results of Surgical Treatment for Non-Hepatic Recurrence"
- Nov 1-8, 1992 Visiting Professor, Surgical Oncology Fellowship Program, Institute of Biomedical Sciences, Taipei, Taiwan, The Republic of China
- Nov 20-21, 1992 Cleveland Clinic Foundation, Cleveland, OH, Presentations - "Surgical Management of Recurrent Rectal Cancer"; and "What is Adequate Follow-up After Colon and Rectal Cancer Surgery"
- Dec 9-11, 1992 Montiforte/Albert Einstein Controversies in Surgery Symposium, New York, NY, Presentation - "Melanoma - Role of Elective Lymph Node Dissection in the Management of Primary Melanoma"

### **1993 PRESENTATIONS**

- January 4-5, 1993 Maimonides Medical Center, Brooklyn, NY, Presentation - Grand Rounds, "Therapy Decisions in Melanoma"
- March 18-21, 1993 Society of Head and Neck Surgeons, and Society of Surgical Oncology, Los Angeles, CA, Presentations - "Combined Sequential Multi-modality Treatment of Head and Neck Cancer, Achieving High Complete Response Rates and Increased 5-year Survival"; "The Contribution of Serum Inhibiting Factors and Immune Cellular Defects to the Depressed Cell Medicated Immunity in the Head and Neck Cancer Patients"; "Laparoscopic Pelvic Node Dissection for Pelvic Malignancies"; "Induction of Human IgM in SCID Mice Reconstituted with Human

Splenic Lymphocytes"; "Interferon Alpha Induces Resistance to Lymphokine Activated Killer (LAK) Cell Mediated Lysis in Human Tumor Cells"; "Ultrasonically Directed Brachtherapy Program for Localized Prostate Cancer in Laparoscopically Staged Patients"; "Cytotoxic Antibodies Generated in the B-16 Murine Melanoma by Formalized Vaccine Shows Cross-Reactivity with B-700 Antigen Expression"; "AgSK1: A Biochemically and Immunologically Distinct Tumor Associated Antigen"; "Differential Growth Regulation by Transforming Growth Factor (TGF) of Pancreatic Carcinoma Cells with Varying Degrees of Metastatic Potential"; "Isolated Pelvic Perfusion Produces Much Greater Drug Localization than Does I.A. Infusion with Filtration"

- April 22, 1993      Sinai Hospital, Baltimore, MD, Presentation - "Hepatoma - Eastern vs. Western Experience"
- May 15-19, 1993      American Society of Clinical Oncology, Orlando, FL, Presentation - "Preoperative Chemotherapy (CT) and Radiation Therapy (RT) for Locally Advanced Pancreatic Cancer"; "Low Frequency Magnetic Fields Can Modulate Cytokine and Immunoglobulin Synthesis in Normal Human Lymphocytes"
- May 19-22, 1993      The American Association for Cancer Research, Orlando, FL, Presentation - "Natural Model of Metastatic Melanoma for Study of Active and Passive Anti-melanoma Immunity"
- May 24-29, 1993      16th International Conference of Surgery, Madrid, Spain, Presentations - "What is the Optimum Therapy for Rectal Cancer in 1993"; "Surgical Management of Hepatoma - Eastern vs. Western Perspective"; "Surgical Treatment of Biliary Tumours in 1993"; "Neoadjuvant Therapy for Cancer of the Pancreas"
- Jun 27-July 2, 1993      18th International Congress of Chemotherapy, Stockholm, Sweden, Presentation - "Drug Removal by Hemoperfusion Charcoal Filters During Isolated Pelvic Chemotherapy (IPC)"
- October 4-7, 1993      Netherlands Cancer Institute/Comprehensive Cancer Center, Amsterdam, Netherlands, Symposium - "Diagnosis and Treatment of Cutaneous Head and Neck Melanoma"; Presentations - "Prognostic Factors"; and "Lymphogenic Metastatic Patterns"
- October 9-14, 1993      American College of Surgeons, San Francisco, CA, Presentation - "Staging Laparoscopic Pelvic Node Dissection - A Useful Adjunct to Cancer Management"



December 6-8, 1993 Southern Surgical Society, Hot Springs, VA, Presentation - "Recurrent Thyroid Cancer: The Role of Surgery versus Radioactive Iodine <sup>131</sup>."

#### **1994 PRESENTATIONS**

March 10-12, 1994 Society of Surgical Oncology, Houston, TX, Presentation - "Preoperative Therapy for Advanced Pelvic Malignancy by Isolated Pelvic Perfusion Using the Balloon Occlusion Technique"

April 7-9, 1994 American Surgical Association, San Antonio, TX, Presentation - "Pelvic Resection of Recurrent Rectal Cancer is Potentially Curative but is Highly Dependent on Patient Selection Based on Known Tumor Risk Factors"

April 22-26, 1994 American Radium Society, Southampton, Bermuda, Presentation - "Preoperative Regional Therapy for Extremity Sarcoma - A Tricentre Study Update"

June 2-4, 1994 European Conference on Gastric Cancer, Tubingen, Germany, Presentation - "American Gastric Cancer Study"

July 5-8, 1994 A.W. Beauregard International Conference: Cancer of the Pancreas, Newport, RI, Organizing Committee Presentation - "Preoperative Chemotherapy and Radiation for Advanced Pancreatic Cancer"

Sept 22-24, 1994 First Annual European-American Conference on Gastrointestinal Oncology: Cancers of the Lower Gastrointestinal Tract, Bordeaux, France, Presentation - "Surgical and Combined Modality Management of Recurrent or Metastatic Colorectal Cancer"

Oct 9-14, 1994 American College of Surgeons, Chicago, IL, Moderator - "Surgical Management of Metastatic Colorectal Cancer" - Presentation - "Introduction to the Problem"

Nov 11, 1994 The Netherlands Cancer Institute, Amsterdam, The Netherlands, Diagnosis and Treatment of Adult Soft Tissue Sarcomas in the Head and Neck, Presentation - "Epidemiology/Clinical Aspects"

#### **1995 PRESENTATIONS**

January 28, 1995 University of Pittsburgh, Pittsburgh, PA, Grand Rounds, Presentation - "Surgical Management of Recurrent Rectal Cancer"

February 1, 1995 Roswell Park Cancer Center, Rochester, NY, Presentation - "Surgical Management of Pelvic Recurrence of Rectal Cancer"

- March 7-9, 1995 8th International Symposium of the Foundation for Promotion of Cancer Research, Tokyo, Japan, Presentation - "Pelvic Resection of Recurrent Rectal Cancer"
- March 23-26, 1995 Society of Surgical Oncology, 48th Annual Cancer Symposium, Boston, MA, Presentations - "Meet the Professor - Chairman: Gynecologic Oncology - Indications for Exenteration"; "Is There a Role for R2 Resection in Gastric Cancer"
- Mar 29-Apr 1, 1995 1st International Gastric Cancer Congress, Kyoto, Japan, Panel-Presentations - "Towards Common Languages for Research and Treatment of Gastric Cancer"; "American Manual and Future Reconditioning", Panel - "National Multi-center Trials the Intention and Results"; "American College of Surgeons - Pattern of Care Study of Gastric Cancer"
- April 10-12, 1995 95th Annual Congress of Japan Surgical Society, Nagoya, Japan, Presentation - "The Changing Role of Radical Resection in Surgical Oncology"
- September 14, 1995 The Royal College of Physicians and Surgeons of Canada, Montreal, Quebec, - Presentation - "Breast Cancer for the General Surgeon"
- Sept 14-17, 1995 2nd International Conference on Gastrointestinal Oncology, Washington, DC, Presentation - "Surgical Options in Gastric Carcinoma: Is There an Optimal Approach?"
- Sept 29-Oct 1, 1995 New England Surgical Society, 1995 Annual Meeting, Montreal, Quebec, Presentation - "Patient Selection for Hepatic Resection of Colorectal Metastases"
- Oct 22-27, 1995 American College of Surgeons, New Orleans, LA, Presentation - "Gastric Cancer - A Continuing Controversy: Does Extra Gastric Lymphadenectomy (R2) Alter Survival?"; Postgraduate course Gallbladder carcinoma; Movie Extended hemipelvectomy, hemisacretomy and total pelvic exenteration for a massive sarcoma of pelvis and upper thigh"

#### **1996 PRESENTATIONS**

- February 7, 1996 Controversies in Surgery, University of Connecticut Health Center, Farmington, CT, Presentation - "The Management of Problems in Recurrent Rectal Cancer"

- March 28-29, 1996 1st International Congress on Pancreatic Cancer, Athens, Greece, Presentation - "Diagnosis and Staging of Pancreatic Cancer"
- July 28-Aug 1, 1996 4th International Conference on Head and Neck Cancer, Panelist - "Adult and Pediatric Head and Neck Sarcoma"; Proffered Session - "Preoperative therapy with Taxol, carboplatin and radiation in advanced head and neck cancer (Stages III and IV) induces a high rate of complete pathologic response at the primary site"; Proffered Session - "Concurrent platinum chemotherapy and hyperfractionated accelerated radiotherapy with late intensification in advanced head and neck cancer"
- Sept 11-14, 1996 15th World Congress of Collegium Internationale Chirurgiae Digestive, Seoul, Korea, Presentation - "Gallbladder Cancer"
- Sept 26-28, 1996 Third International Conference on Gastrointestinal Oncology: Pancreatic and Hepatobiliary Cancer - Co-Chairman, Session 1 - Hepatocellular Carcinoma: Epidemiology, Etiology, Screening, Prevention, Presentation "Cryosurgery for Hepatocellular Carcinoma"
- October 6-11, 1996 American College of Surgeons, Clinical Congress, Presentations - "Diseases of the Liver, Biliary Tract and Pancreas"; "Role of Splenectomy in Gastric Cancer Surgery - Adverse Effect of Elective Splenectomy on Long-term Survival"
- Oct 24-25, 1996 Uniformed Services University of Health Sciences, Walter Reed Army Medical Center, Bethesda, MD, Presentation - "Surgical Management of Gastric Cancer"; "Retrieval Surgery for Recurrent Colorectal Cancer"; National Naval Medical Center, Presentation "Cancer of the Gallbladder"

#### **1997 PRESENTATIONS**

- March 20-23, 1997 The Society of Surgical Oncology, Inc. Chicago, IL, Presentation - "Preoperative chemotherapy(CT), Radiation, and Surgical Resection of Locally Advanced Pancreatic Cancer"
- April 9-12, 1997 The Society of Head and Neck Surgeons, Cancun, Mexico, Presentation-Poster Presentation - "The Use of Clonogenic(chemosensitivity) Assay to Predict Survival of Patients with Carcinoma of the Head and Neck." Paper - "Preoperative Chemoradiation(Paclitaxel and Carboplatin) Coupled with Aggressive Resection as Needed Ensures Nearly a Total Control of Advanced Head and Neck Cancer (Stages III and IV)"

- April 27-30, 1997 2nd International Gastric Cancer Congress, Munich, Germany. Presentations - "Role of Splenectomy in Gastric Cancer Surgery - Adverse Effect of Elective Splenectomy on Long-term Survival.", "Phase I/II study of Neoadjuvant Paclitaxel and Concurrent Radiation for Locally Advanced Gastric Cancer"
- June 21-23, 1997 XIII Congress of the Argentina Association of Clinical Oncology, Buenos Aires, Argentina. Presentations "New Strategies in Pancreatic Cancer", "Pelvic Recurrence in Rectal Carcinoma", "Gastrointestinal Tumors"
- November 7, 1997 Brown University Oncology Group, Providence, Rhode Island. New Strategies in the Treatment of Melanoma - Moderator
- Nov 13-15, 1997 Japanese Society for Clinical Surgery, Osaka, Japan. Presentation "Surgical Management of Pelvic Recurrence of Rectal Cancer"

#### **1998 PRESENTATIONS**

- Jan 27-31, 1998 1998 Phoenix Surgical Society Symposium, Phoenix, AZ. Presentations- "Surgical Management of Liver Metastases from Colorectal Cancer and Recurrent Rectal Cancer," "Is Breast Cancer in the Elderly Understaged and Undertreated?", "Preoperative Chemoradiation Therapy of Pancreatic Cancer"
- March 12, 1998 Surgical Grand Rounds - Baystate Medical Center, Springfield, MA. "Surgical Management of Recurrent Rectal Cancer"
- April 18, 1998 American Cancer Society - Regional Chapter, Providence, RI. "Breast Cancer in the Elderly"
- April 25, 1998 Surgical Grand Rounds - Wayne State University, Detroit, MI. "Pre-operative Therapy for Carcinoma of the Pancreas"
- May 2, 1998 Surgical Grand Rounds, Boston Medical Center, Boston, MA. "Preoperative Treatment for Cancer of the Pancreas"
- May 4, 1998 The American Society of Colon and Rectal Surgeons, San Antonio, TX. "Pelvic Resection of Recurrent Rectal Cancer - Technical Considerations and Outcomes"
- May 16-19, 1998 American Society of Clinical Oncology, Los Angeles, CA. Neoadjuvant Paclitaxel, Cisplatin and Radiation for Esophageal Cancer. Alternating Hepatic Artery Infusion of 5-Fluorodeoxyuridine(FUdR) Dexamethasone(DEX) and Leucovorin with Systemic Continuous

Infusion(CI) of 5-Fluorouracil and Leucovorin is Associated with Apparent Survival Benefit(median 18 months) in Patients with Unresectable Liver Metastases from Colorectal Cancer(CRC)", "Concurrent Paclitaxel, Carboplatin and Radiotherapy in Advanced Head and Neck Cancers: A Phase II Study"

- Aug 24-28, 1998 17th UICC International Cancer Congress, Rio De Janeiro, Brazil Moderator - Rectal Cancer, Presentations - "Impact of Prognostic Factors on the Management of Rectal Cancer", "Preoperative versus. Postoperative Radiation for Primary Rectal Cancer"
- Sept. 16-18, 1998 Fifth Annual International Conference on Gastrointestinal Oncology, Cancers of the Upper Gastrointestinal Tract: Gastric and Esophageal Carcinoma and Gastric Lymphoma, Bordeaux, France. Presentation - "Surgical Patterns for Gastric Cancer in the United States"
- October 2, 1998 BrUOG Hormonal Therapy for Breast Cancer in 1999 and Beyond, Brown University School of Medicine, Providence, RI
- Oct 24-30, 1998 American College of Surgeons, Orlando, FL, Presentation:- "Managing Pelvic Recurrence"
- Nov 11-15, 1998 The Society of Pelvic Surgeons, Sarasota, FL, Presentation: "Composite Pelvic Resection: An Approach to Advanced Pelvic Cancer"

### **1999 PRESENTATIONS**

- January 13-14, 1999 St. Elizebeth's Hospital, Boston, MA Invited speaker - Grand Rounds. "Surgical Management of Recurrent Rectal Cancer," "Preoperative Chemotherapy and Radiation Therapy for Pancreatic Cancer"
- March 2-3, 1999 Washington Hospital, St. Louis, MI. Invited lecture - "Surgical Management of Hepatic Metastasis"
- March 4-7, 1999 Society of Surgical Oncology Meetings, Orlando, FL. Presentations - "Immunization of Mice with Melanoma Cells Transfected to Secrete the Superantigen Staphylococcal Enterotoxin A", "Thin <1mm Level III and IV Melanomas Higher Risk Lesions for Regional Failure" and Warrant Sentinel Lymph Node Biopsy". Poster Sessions - "Effects of Paritaxol and Ceramide on Human Squamous Carcinoma Cell Line TU138 in vitro and in vivo" and "Alternating Hepatic Artery Infusion with Systemic Continuous Infusion(CI) for Metastatic Colorectal Cancer is Associated with High Rates of Tumor Regression (67%) and Survival (Median 24 months)"

- March 30, 1999 North Shore University Hospital, Manhasset, New York. Grand Rounds - "Surgical Management of Recurrent Rectal Cancer"
- April 1, 1999 Massachusetts General Hospital, Boston, MA. Case Presentation Conference - Department of Pathology - Discussant
- April 7-8, 1999 Royal Victoria Hospital, Montreal, Quebec. Presentations-"Gastric Cancer, Neoadjuvant Therapy, Node Dissection and Other Issues" and "Surgical Options for Hepatic Metastases of Colorectal Cancer", McGill University, Montreal, Quebec "Neoadjuvant Therapy of Pancreatic Cancer"
- April 21-23, 1999 International Cancer Conference, Aventura, FL. Presentation -"Local-Regional Therapies in Colon Cancer"
- May 1, 1999 Grand Rounds - Rhode Island Hospital. "The Role of Surgery in Aggressive Chemoradiation Protocols for Advanced Squamous Cancer of the Head and Neck(Stage III & IV)"
- May 21-22, 1999 Grand Rounds - Berkshire Medical , Pittfield, MA
- June 3, 1999 Grand Rounds - Roger Williams Medical Center, "Surgical Management of Squamous Cancer of the Skin"
- July 23, 1999 Grand Rounds - New England Baptist Hospital. "Composite Pelvic Resection: An Approach to Advanced Pelvic Cancer"
- Sept 13-14, 1999 Grand Rounds - Dartmouth, New Hampshire, "Head & Neck Cancer"
- October 4, 1999 Grand Rounds - Boston University School of Medicine, "Management of Liver Metastases from Colorectal Cancer"
- October 10, 1999 American College of Surgeons, Surgical Biology Club III, "Ceramide Provides an Apoptotic Death Signal Which Potentates Antitumor Taxol"
- October 19-23, 1999 9<sup>th</sup> World Congress of the International Gastro-Surgical Club, Nagasaki, Japan. "Is Surgical Resection Indicated for Patients With Stage III Pancreatic Cancer?"
- November 14, 1999 New England Cancer Society 60<sup>th</sup> Anniversary, Providence, RI. "Multioption Therapeutic Strategy for Hepatic Metastases of Colorectal Cancer" and "Isolated Chemotherapeutic Perfusion of the Pelvis for Advanced or Unresectable Malignancy, and Synergistic Action of Paclitaxel and Anti-Fasr Antibody in the Induction of Apoptosis of

Leukemic Cells is Dependent of Caspase-8 Mediated Signaling Pathway."

## 2000 PRESENTATIONS

- March 15-19, 2000 The Society of Surgical Oncology, New Orleans, Louisiana – Presentations: "Isolated Chemotherapeutic Perfusion of the Pelvis for Advanced or Unresectable Malignancy," "Preoperative Chemoradiation for High Stage Extremity Sarcoma Facilitates Limb Salvage and Excellent Long Term Local Control," "Surgical Resection is Necessary to Maximize Tumor Control in Function Preserving, Aggressive Chemoradiation, Protocols for Advanced Squamous Cancer of the Head and Neck (Stage III & IV)."
- March 25-26, 2000 The 54<sup>th</sup> Scientific Meeting of the Surgical Association R.O.C., Taipei, Taiwan – Presentation: "The Yin and Yang of Rectal Cancer."
- April 5-8, 2000 The 10<sup>th</sup> European Society of Surgical Oncology, Groningen, The Netherlands – "Surgical Management of Pelvic Recurrence of Rectal Cancer."
- April 14, 2000 Brown University School of Medicine – Selected Topics in Hepato-Biliary Disease, "Surgical Resection of Bile Duct Cancers."
- May 20-23, 2000 The 36<sup>th</sup> Annual meeting of the American Society of Clinical Oncology, New Orleans, Louisiana. Presentation: "Preoperative Therapy With Reduced Dose Paclitaxel and Carboplatin and Radiation Achieves Similar Complete Response Rate to a High Dose Regimen, But With Reduced Toxicity" and Synergistic Action of Paclitaxel and Anti-FASR Antibody in the Induction of Apoptosis of Leukemic Cells in Dependent On Caspase-8 Mediated Signalling Pathway."
- June 8, 2000 Paul J. Grotzinger, M.D. Lecture, Fox Chase Cancer Center, Philadelphia, Pennsylvania. Presentation: "Surgical Management of Pelvic Recurrence of Rectal Cancer."
- July 29-Aug 3, 2000 5<sup>th</sup> International Conference on Head and Neck Cancer, San Francisco, California. Presentations: "Ceramide Enhances Paclitaxel-Induced Apoptosis of a Human Squamous Carcinoma Cell Line In Vitro And In Vivo Caspase-8 Signaling Pathway;" "Preoperative Therapy with Reduced Dose Paclitaxel and Carboplatin and Radiation Achieves A Similar Complete Response Rate To A High Dose Regimen, But

**With Reduced Toxicity In Patients With Advanced Head and Neck Squamous Cancer;" and Neoadjuvant Therapy For Locally Advanced (Stage III & IV) Squamous Cell Cancer of the Head And Neck."**

**August 24, 2000** Case Records of the Massachusetts General Hospital; A 47 year old man with recurrent pancreatitis and cystic pancreatic mass. New Engl Journal of Med, 343:8;563-570.

**October 10-15, 2000** IV Congreso Integrado, Invited Professor, Santiago, Chile. Presentation: "How Extended Should Be a Gastrectomy."

### **2001 PRESENTATIONS**

**February 21, 2001** Grand Rounds – Rhode Island Hospital, "Therapeutic Options For Gastric Cancer"

**February 24,  
March 4, 2001** 5<sup>th</sup> World Conference on Melanoma, Venice, Italy. Presentation: "Age and lesion site are major factors influencing the sensitivity of sentinel node biopsy."



- March 15-18, 2001 Society of Surgical Oncology's 54<sup>th</sup> Annual Cancer Symposium, March 15-18, 2001, Marriott Wardman Hotel, Washington, D.C. Presentation: "Paclitaxel-Induced Apoptosis of a Human Squamous Carcinoma is Enhanced by Either Ceramide or Anti-FAS Receptor Antibody and Appears to Mediate Through the Caspase-8 Signaling Pathway."
- April 9, 2001 Souza K, Belliveau JF, Wanebo HJ. Clinical pharmacology of adriamycin and cis-platinum in isolated pelvic perfusion: evaluation of UV-visible methodology for adriamycin pharmacokinetics. American Chemical Society Meeting, Rhode Island Section at Providence College, Department of Chemistry, Providence College and Roger Williams Medical Center/Boston University.
- May 14-16, 2001 American Head and Neck Society, May 14-16, 2001, Palm Desert, California. Presentations: "Changing patterns of failure of head and neck cancer" and "Neoadjuvant therapy for high stage head and neck cancer achieves excellent loco-regional control, but is still plagued by distant failure."
- May 12-15, 2001 American Society of Clinical Oncology, May 12-15, 2001, San Francisco, California. Presentation: "Preoperative chemotherapy with paclitaxel and carboplatin and radiation achieves high rates of local regional control, but continued erosion of survival by distant disease."
- July 21-29, 2001 Society of Pelvic Surgeons Meeting, Oslo-Bergen, Norway. Presentation: "Isolated chemotherapeutic perfusion of the pelvis for advanced or unresectable malignancy."
- October 7-12, 2001 87<sup>th</sup> Annual Clinical Congress of the American College of Surgeons. Movie Presentation: "Transhiatal laparoscopic esophagogastrrectomy is an ideal procedure for selected patients with early stage distal esophageal cancer."
- November 9-10, 2001 North Pacific Surgical Association Eighty-Eighth Annual Meeting. Presentations: "Surgical Management of Recurrent Rectal Cancer" and "Multioption Therapeutic Strategy for Hepatic Metastases of Colorectal Cancer"; Victoria, British Columbia.

## **2002 PRESENTATIONS**

- March 13-17, 2002    The Society of Surgical Oncology's 55<sup>th</sup> Annual Cancer Symposium. Poster Presentations: "Neoadjuvant Therapy Induces a 30% Complete pathologic Response, But Does Not Affect Outcome In Resectable Esophageal Cancer" and Complications of Hepatic Artery Infusion Chemotherapy: The Need for Active Surveillance and Early Detection", Denver, Colorado.
- April 9-13, 2002    102<sup>nd</sup> Annual Congress of the Japan Surgical Society. Presentation: "Advanced Pelvic Malignancy – The Continued Quest for Solution", Kyoto, Japan.
- May 18-21, 2002    2002 Annual meeting of the American Society of Clinical Oncology. Presentations: "Isolated chemotherapeutic perfusion of the pelvis for advanced or unresectable malignancy" and "Neoadjuvant chemotherapy with paclitaxel (P) and carboplatin (C) and concurrent radiation 45-70Gy is associated with a high rate of laryngeal preservation (92%) in patients with high staged larynx cancer", Orlando, Florida.
- Presented in part at the Thirty-Eighth Annual Meeting of the American Society of Clinical Oncology, Orlando, FL. "Herceptin, paclitaxel, cisplatin, and radiation for adenocarcinoma of the esophagus: a Phase I study."
- May 27-June 1, 2002    XXV International Meeting of Surgery – What's New In Surgery", Madrid, Spain. Presentations: "Gastric Cancer – Role of Adjuvant/Neoadjuvant Therapy", "Esophageal Cancer. Is It Of Value?", "Translaparoscopic Approach" (Video), and "Hepatic Metastases from Colorectal Cancer: A Multioption Approach., Treatment of Advanced Colorectal Cancer."
- September 12-14, 2002    European Association of Coloproctology, Scientific and Third Annual General Meeting, Erlangen, Germany. Presentation: "The Role of Regional Chemotherapy"
- September 18, 2002    Grand Rounds, Rhode Island Hospital, Providence, RI. Presentation: "Surgical Management of Recurrent Rectal Cancer"
- November 7-9, 2002    9<sup>th</sup> International Conference on Gastrointestinal Cancer: Cancer of the Upper GI Tract", Palais des Congres, Arcachon, France. Presentation: "Surgical Patterns for Gastric Cancer in the United States."

Nov 16-19, 2002 V International Symposium, Sphincter Saving Surgery for Rectal Cancer, Milan, Italy. Presentation: "A New Challenge for Colorectal Cancers: The Pelvic Relapses."

### **2003 PRESENTATIONS**

February 12, 2003 Grand Rounds, Rhode Island Hospital, Providence, RI. Presentation: "Potential Role of the Apoptosis Signal (Ceramide) in Cancer Therapy".

Feb 27-Mar 3, 2003 2003 Americas Hepato-Pancreato-Biliary Congress, Miami Beach, Florida. Presentation: "Hepatic Artery Infusion: Technical Considerations, Benefits, and Pitfalls".

May 3-7, 2003 Fifth International Gastric Cancer Congress, Rome, Italy. "Taxol and Radiation May Enhance Opportunity for Curative Resection and Prolonged Survival in Patients With Proximal Gastric Cancer".

May 30-June 3 American Society of Clinical Oncology, Chicago, Illinois. "Mandibular Squamous Cancer is Poorly Responsive to Neoadjuvant Chemoradiation, Unlike Other Head and Neck Sites, Requiring Resection for Long-term Control."

October 23-25 Tenth International Conference on Gastrointestinal Oncology, Williamsburg, Virginia.

### **2004-2005 UNDER REVISION**

### **2006 PRESENTATIONS**

2006: Safran H, Suntharalingam M, Wanebo H, Ng T, Krasna M, Doyle L, Benton D, Daly B, Spector J, Dopetrillo T. Cetuximab, paclitaxel, carboplatin, and radiation for esophageal and gastric cancer. Proceedings (Post-Meeting Edition) ASCO Gastrointestinal Cancer Symposium, January, pg115.

2006: Isolated chemotherapeutic perfusion of pelvis as neoadjuvant or palliative therapy for Advanced cancer of the rectum or anorectum. Proceedings (Post-Meeting Edition) ASCO Gastrointestinal Cancer Symposium, January, p263.

September 15, 2006 New England Surgical Society, Groton, Connecticut. Neoadjuvant Chemo radiation for high grade extremity sarcoma. Presented by Dr. Wanebo

- Sept 28-29, 2006      Colorectal Cancer Consensus Conference, Lackenow Hospital, Philadelphia  
Organized by Dr. Gerald Marks, Dr. Wanebo was a participant and chaired Session.
- October 5-6, 2006      Hepatobiliary Surgery, Memorial Sloan Kettering Cancer Center, New York City, NY. Half Century of Progress-Participated in conference.
- Oct 7-11, 2006      American College of Surgeons Meetings  
1. Society of Surgical Oncology (Program director Meeting)  
2. Sentinel Lymph Node Meetings (Program director)  
3. Surgical Biology Club III-Program and other general ACS meeting  
4. Attended ACS General Meeting
- November 18-23      International Meeting, Milan, Italy. Sphincter saving surgery for Rectal Cancer. Dr. Wanebo presented "Surgical Management of Recurrent Rectal Cancer".

### **2007 PRESENTATIONS**

- January 19-21, 2007      GI Conference, San Francisco, CA. Dr. Wanebo presented: The shc protein as Predictor of response and outcome in stage II Colon Cancer.
- February 23-25, 2007      Regional Therapy Conference, San Juan, Puerto Rico. Dr. Wanebo presented Neoadjuvant Pelvic Perfusion for Advanced Rectal Cancer.
- March 15-18, 2007      Society for Surgical Oncology Meeting, Washington D.C.  
Dr. Wanebo organized and chaired meeting. Growth factors in molecular Analysis and therapy of malignancy-Sentinel Lymph Node Working group conference. Presented 2 posters: Surgical Management of Recurrent Rectal Cancer and Ceramide potentiates anti tumor effect of Oxaliplatin and Gemcitabine.
- March 18, 2007      Dr. Wanebo organized and chaired multidisciplinary advances in Head and Neck Cancer.
- May 2-5, 2007      2<sup>nd</sup> International Cancer Symposium, San Francisco, CA. Presented by Harold Wanebo. Symposium on vascular and lymphatic metastases. Targeting of Small Molecules in Cancer Therapy to VEGFR and EGFR, to the Cancer Patients.
- May 8-9, 2007      American Society for Clinical Lab Science- Central New England 59<sup>th</sup> Annual Clinical lab science convention, Providence, RI. Presented by Dr. Wanebo. Evolution of Biologic Therapy for Cancer.

- June 1-4, 2007 American Society of Clinical Oncology, Chicago, IL. Phase II evaluation of Cetuximab C225 combined with Induction Paclitaxel and Carboplatin followed by C225, Paclitaxel, Carboplatin, and Radiation for Stage III/IV Operable Squamous Cancer of the Head and Neck: A Trial of the Eastern Cooperative Oncology Group (E2303) Presented by Dr. Wanebo
- July 2007 Cetuximab with Concurrent Chemoradiation for esophagogastric Cancer: Assessment of Toxicity. Safran, H., Suntharalingam, M, Dipetrillo, T, Ng, T., Doyle,A., Krasna, M., Plette,A., Evans,D., Akerman,P., Wanebo,H., Spector,J., Kennedy,N., Kennedy,T.
- October 7-10, 2007 American College of Surgeons. New Orleans, LA. Presentation to Surgery Biology Club III "The Apoptosis signal Ceramide enhances the anti tumor effect of all the major drug classes tested.
- November 20-23, 2007 Surgical Management of Hepatic Colorectal Metastases. Sao Paulo, Brazil.  
 1. APR for advanced rectal cancer (tips and tricks)  
 2. Abdominal sacral resection for recurrent rectal cancer

### **2008 PRESENTATIONS**

- January 25-27, 2008 Poster presentation: Cetuximab-based neoadjuvant chemoradiation appears to facilitate surgical resection in patients with locally advanced esophageal and gastric cancer. H.J. Wanebo, T. Dipetrillo, T. Kennedy.
- Poster presentation: Hepatic arterial infusion (HAI) Oxaliplatin in advanced hepatocellular cancer (HCC): A phase I Brown University Oncology Group study. R. Rathore, G. Soares, J. Bass, B. McNulty, K. Charpentier, D. Iannitti, H.J. Wanebo, H.Safran.
- Poster presentation: Hepatic artery infusion as a survival enhancing strategy in surgical therapy of hepatic metastases from colorectal cancer. H.J. Wanebo, K.Varker, G. Begossi, C. Taneja, F.Cummings.
- February 17-18, 2008 Regional Cancer Therapy Conference. Hepatic Artery infusion is a survival enhancing strategy in Surgical therapy of Hepatic Metastases from colorectal cancer.
- March 13-16, 2008 Society for Surgical Oncology. The Apoptosis Signal Ceramide (C6) significantly enhances the anti tumor effects of a variety of chemo therapeutic drug classes. D. Shrayar, J. Belliveau, H.J.Wanebo.

**Poster: Hepatic artery infusion is a survival enhancing strategy in surgical therapy of hepatic metastases from colorectal cancer. K. Varker, C.Taneja, G.Begossi, H.J.Wanebo.**

**EXHIBIT B**

Applicants: Harold J. Wanebo and Shashikant Mehta  
U.S. Serial No.: 09/287,884  
Filed: April 7, 1999

### **% SURVIVAL**

<b>Week</b>	<b>Gr. 1</b>	<b>Gr. 2</b>	<b>Gr. 3</b>	<b>Gr. 4</b>	<b>Gr. 5</b>	<b>Gr. 6</b>	<b>Gr. 7</b>	<b>Gr. 8</b>
0	100	100	100	100	100	100	100	100
1	100	100	100	100	100	100	100	100
2	80	100	100	100	100	100	100	100
3	0	40	60	100	60	100	80	100
4	0	0	0	40	40	60	60	100
5	0	0	0	0	0	60	60	80
6	0	0	0	0	0	60	60	80

#### **Chemotherapy:**

- Gr. 1 None
- Gr. 2 Ceramide 6 (10.0 mg/kg)
- Gr. 3 Taxol (3.0 mg/kg)
- Gr. 4 Oxaliplatin (2.5 mg/kg)
- Gr. 5 Cisplatin (2.5 mg/kg)
- Gr. 6 Ceramide 6 + Taxol
- Gr. 7 Ceramide 6 + Oxaliplatin
- Gr. 8 Ceramide 6 + Cisplatin

Applicants: Harold J. Wanebo and  
Shashikant Mehta  
Serial No.: 09/287,884  
Filed: April 7, 1999  
**Exhibit B**



## **EXHIBIT C**

**Applicants:** Harold J. Wanebo and Shashikant Mehta  
**U.S. Serial No.:** 09/287,884  
**Filed:** April 7, 1999

### MEAN SURVIVAL TIME OF MICE (days)

	<b>Gr. 1</b>	<b>Gr. 2</b>	<b>Gr. 3</b>	<b>Gr. 4</b>	<b>Gr. 5</b>	<b>Gr. 6</b>	<b>Gr. 7</b>	<b>Gr. 8</b>
	17.8 (±1.1)	20.8 (±1.7)	23.0 (±2.4)	27.4 (±2.2)	25.6 (±3.2)	35.2 (±4.2)	35.0 (±4.4)	40.6 (±1.4)
<b>vs. Control</b>	N/A	P<0.05	P<0.05	P<0.005	P<0.1	P<0.005	P<0.005	P<0.005

#### Chemotherapy:

- Gr. 1 None
- Gr. 2 Ceramide 6 (10.0 mg/kg)
- Gr. 3 Taxol (3.0 mg/kg)
- Gr. 4 Oxaliplatin (2.5 mg/kg)
- Gr. 5 Cisplatin (2.5 mg/kg)
- Gr. 6 Ceramide 6 + Taxol
- Gr. 7 Ceramide 6 + Oxaliplatin
- Gr. 8 Ceramide 6 + Cisplatin

## **EXHIBIT D**

**Applicants:** Harold J. Wanebo and Shashikant Mehta  
**U.S. Serial No.:** 09/287,884  
**Filed:** April 7, 1999

**MEAN VOLUME OF PRIMARY TUMORS (cm<sup>3</sup>)**

	<b>Gr. 1</b>	<b>Gr. 2</b>	<b>Gr. 3</b>	<b>Gr. 4</b>	<b>Gr. 5</b>	<b>Gr. 6</b>	<b>Gr. 7</b>	<b>Gr. 8</b>
	1.56 (±0.2)	1.69 (±0.3)	1.83 (±0.4)	1.76 (±0.2)	1.83 (±0.13)	1.19 (±0.28)	0.75 (±0.05)	1.16 (±0.18)
<b>vs. Control</b>	N/A	P>0.1	P>0.1	P>0.1	P>0.1	P>0.1	P<0.025	P<0.1

**Chemotherapy:**

- Gr. 1 None
- Gr. 2 Ceramide 6 (10.0 mg/kg)
- Gr. 3 Taxol (3.0 mg/kg)
- Gr. 4 Oxaliplatin (2.5 mg/kg)
- Gr. 5 Cisplatin (2.5 mg/kg)
- Gr. 6 Ceramide 6 + Taxol
- Gr. 7 Ceramide 6 + Oxaliplatin
- Gr. 8 Ceramide 6 + Cisplatin

Applicants: Harold J. Wanebo and  
Shashikant Mehta

Serial No.: 09/287,884

Filed: April 7, 1999

**Exhibit D**

## **EXHIBIT E**

Applicants: Harold J. Wanebo and Shashikant Mehta  
U.S. Serial No.: 09/287,884  
Filed: April 7, 1999

**MEAN RATE OF TUMOR DEVELOPMENT (cm<sup>3</sup>/day)**

	<b>Gr. 1</b>	<b>Gr. 2</b>	<b>Gr. 3</b>	<b>Gr. 4</b>	<b>Gr. 5</b>	<b>Gr. 6</b>	<b>Gr. 7</b>	<b>Gr. 8</b>
	0.086 (±0.07)	0.082 (±0.006)	0.078 (±0.01)	0.054 (±0.009)	0.069 (±0.013)	0.035 (±0.009)	0.024 (±0.005)	0.029 (±0.005)
<b>vs. Control</b>	N/A	P>0.1	P>0.1	P<0.005	P>0.1	P<0.025	P<0.005	P<0.005

**Chemotherapy:**

- Gr. 1 None
- Gr. 2 Ceramide 6 (10.0 mg/kg)
- Gr. 3 Taxol (3.0 mg/kg)
- Gr. 4 Oxaliplatin (2.5 mg/kg)
- Gr. 5 Cisplatin (2.5 mg/kg)
- Gr. 6 Ceramide 6 + Taxol
- Gr. 7 Ceramide 6 + Oxaliplatin
- Gr. 8 Ceramide 6 + Cisplatin

## **EXHIBIT F**

Applicants: Harold J. Wanebo and Shashikant Mehta  
U.S. Serial No.: 09/287,884  
Filed: April 7, 1999

**MEAN WEIGHT OF PRIMARY TUMORS (g)**

	<b>Gr. 1</b>	<b>Gr. 2</b>	<b>Gr. 3</b>	<b>Gr. 4</b>	<b>Gr. 5</b>	<b>Gr. 6</b>	<b>Gr. 7</b>	<b>Gr. 8</b>
	1.56 (±0.08)	1.04 (±0.12)	0.82 (±0.18)	0.70 (±0.08)	1.28 (±0.6)	1.26 (±0.2)	0.92 (±0.19)	0.92 (±0.25)
<b>vs. Control</b>	N/A	P<0.01	P<0.01	P<0.005	P>0.1	P<0.1	P<0.0025	P<0.05

**Chemotherapy:**

- Gr. 1 None
- Gr. 2 Ceramide 6 (10.0 mg/kg)
- Gr. 3 Taxol (3.0 mg/kg)
- Gr. 4 Oxaliplatin (2.5 mg/kg)
- Gr. 5 Cisplatin (2.5 mg/kg)
- Gr. 6 Ceramide 6 + Taxol
- Gr. 7 Ceramide 6 + Oxaliplatin
- Gr. 8 Ceramide 6 + Cisplatin



## **EXHIBIT G**

Applicants: Harold J. Wanebo and Shashikant Mehta  
U.S. Serial No.: 09/287,884  
Filed: April 7, 1999

**MEAN BODY WEIGHT (g)**

<b>Gr. 1</b>	<b>Gr. 2</b>	<b>Gr. 3</b>	<b>Gr. 4</b>	<b>Gr. 5</b>	<b>Gr. 6</b>	<b>Gr. 7</b>	<b>Gr. 8</b>
17.2 (±0.7)	17.0 (±0.9)	17.4 (±0.9)	15.6 (±0.9)	16.6 (±0.4)	20.0 (±1.6)	20.2 (±1.6)	20.0 (±1.1)

**Chemotherapy:**

- Gr. 1 None
- Gr. 2 Ceramide 6 (10.0 mg/kg)
- Gr. 3 Taxol (3.0 mg/kg)
- Gr. 4 Oxaliplatin (2.5 mg/kg)
- Gr. 5 Cisplatin (2.5 mg/kg)
- Gr. 6 Ceramide 6 + Taxol
- Gr. 7 Ceramide 6 + Oxaliplatin
- Gr. 8 Ceramide 6 + Cisplatin